

## 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.’

Brussels, 2 June 2004.

*The President*  
of the European Economic and Social Committee  
Roger BRIESCH

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### **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’**

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(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 409<sup>th</sup> 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.

1.4 A report 'Global Competitiveness in Pharmaceuticals: a European perspective <sup>(1)</sup>' (usually referred to as the Pammolli Report) was presented to the Commission in November 2000. The Report identified a number of issues that needed to be addressed and concluded 'Europe was lagging behind the USA in its ability to generate, organise and sustain innovative processes that are increasingly expensive and organisationally complex'.

1.5 The background to the Communication from the Commission is to consider the issues identified both in the Pammolli Report and subsequent reports because the pharmaceutical industry is recognised as playing an important health, social and economic role in the European Union.

1.6 Important progress has been made with the establishment of the Community marketing authorisation procedures and the creation of the European Medicines Evaluation Agency (EMA) in 1995.

1.7 In March 2000 a health policy advisory group to the Commission stated that the public health goal of the pharmaceutical sector is 'to make readily accessible, efficacious, high quality safe medicines, including the more recent and innovative ones, to all those who need them, regardless of their income or social status' <sup>(2)</sup>.

1.8 The Commission remains committed to completing the single market in pharmaceuticals by encouraging research and development <sup>(3)</sup> through making the EU more attractive for investment and establishing systems which provide more patient choice through the affordability and availability of medicines.

1.9 In addition the Commission set up a new High Level Group on Innovation and the Provision of Medicines (G10 Medicines) <sup>(4)</sup> which was intended to take a fresh look at the problems facing the pharmaceutical sector in relation to national and community competencies which govern it and to come up with creative solutions.

1.10 The G10 Group published its report 'High Level Group on innovation and provision of medicines' in May 2002 and the consensus approach it adopted in the 14 recommendations made by the Group forms the basis of the Commission's 'Call for Action' on which the EESC is invited to provide an opinion (Appendix).

1.11 The position has been further reinforced by the Council Resolution on 'Pharmaceuticals and Public Health Challenges — Focusing on Patients' <sup>(5)</sup>.

<sup>(1)</sup> Enterprise papers No 1/2001.

<sup>(2)</sup> Created by the High Level Committee on Health.

<sup>(3)</sup> Internal Market Council Conclusions 18.5.1998.

<sup>(4)</sup> European Commission High Level Group on Innovation and Provision of Medicines a Call for action. G10 Medicines 7.5.2002.

<sup>(5)</sup> Council Resolution of 2.12.2003.

## 2. Purpose of the communication

2.1 The purpose of the communication is to 'set out how the Commission sees the G10 recommendations being taken forward in the current context'. In areas of national competence the Commission sets out a proposed direction it believes Member States could take and what the Commission can do to facilitate the process and in particular to have the important function of monitoring change and effectiveness.

2.2 In this context the Commission sets out in its communication five broad themes which encompass the issues within Europe:

- benefits to patients;
- developing a competitive European based industry;
- strengthening the EU science base;
- medicines in an enlarged European Union;
- Member States learning from each other.

## 3. The text — general comments

3.1 The pharmaceutical industry is one which has complex inter-relationships with health care systems, research, patients, and competitor companies. It is a large employer within the European Union. The industry is required to be innovative and to function well with different systems in the USA and Japan. The emphasis of this Communication is to engender an integrated approach in order to build advantage for the industry and patients as well as to stimulate its continued development as a major contributor to a dynamic knowledge-based, competitive economy in Europe. The EESC acknowledges that this is a major task.

3.2 The competitiveness of the industry is a matter of considerable concern and comparisons are frequently made with the success of the industry in the USA. It is important to emphasise that this is not because of any intrinsic weakness on the part of the pharmaceutical industry, but is the consequence of the fragmentation of the markets, which remain highly differentiated at national level. This results in a fragmented approach to research, innovation and the classification of medicines into prescription and non-prescription categories. This arises because of dependence on the decision-making process of 25 national governments and the resulting differences in their social security and health policies. This affects investment in research and development, the availability of products and ultimately the benefit to patients in a consistent way across the Member States.

3.3 It is vitally important that the role of the industry is considered in relation to the established health care systems in the Member States, how and to what extent they are financed and how to ensure that patients in each of the Member States have access to every medicine authorised in the EU. Whilst this is a key objective for the Commission the EESC recognises the divergence that exists in ensuring the availability of medicines and the ability within the Member States to fund this aspiration and the EESC is particularly concerned about the potential impact on the accession States.

3.4 The EESC recognises the growing importance of involving patients in decision making and in developing partnerships between public, private and patient groups for mutual benefit. Whilst the EESC welcomes the inclusive approach proposed by the Commission it was disappointed that the G10 group on medicines did not have a wider representative base.

3.5 The EESC acknowledges that evidence shows the decline in the competitiveness of the European pharmaceutical industry. However, whilst weaknesses in the European model for the industry have been identified, it is important to focus on the available skills, established structures and achievements within Europe rather than assuming that the US model is necessarily the best or only way forward taking into account all the interests at stake. The key aim in the EU model is to achieve efficiency of the health-care systems that meets the needs of patients, whether medical, economic or social, whilst promoting the economic activities of the pharmaceutical industry.

3.6 The basis of the Communication from the Commission is very wide and the EESC would draw attention to its previously expressed concerns that the steps required to achieve progress in these areas have been slow to date and is concerned as to how the Commission will be able to achieve more rapid progress in the light of this communication <sup>(1)</sup>.

3.7 The Commission emphasises the importance of monitoring and evaluating the achievements against defined performance indicators. The EESC echoes these concerns about the lack of consistent statistical information and evidence on which to judge progress and proposed development. Better processes are required with which to define what information should be collected and the EESC would wish to see a much more proactive and transparent system being established.

3.8 It is acknowledged that the pharmaceutical sector provides high quality employment that goes beyond the immediate industry employees as it involves other research

sectors, allied companies, universities and the health sector. There is, however, concern that without a more coherent approach to research and innovation in Europe, accompanied by adequate investment, that skilled employees will be lost to the sector in Europe.

3.9 Whilst the EESC is aware of the difficulties in achieving the single market within existing and future Member States it wishes to see clear strategies in place to achieve this goal in the pharmaceutical industry because of the divergence between EU level and national competencies on the marketing of medicinal products and particularly because of the differing health care and funding systems in each Member State. The EESC would again emphasise the great importance it attaches to the fact that protection of human health should take precedence over all other areas of regulation as stated in previous opinions and because of the public health goal of the pharmaceutical sector to make high quality safe medicines, including innovative ones available to all who need them regardless of their income or social status <sup>(2)</sup>.

#### 4. Proposed action from the Commission

##### 4.1 *Benefits to patients*

4.1.1 The responsibility for health care is becoming increasingly shared with patients taking a more active interest in their own health and care options. The importance of involving patients has been recognised by the Commission and the EESC welcomes the emphasis on creating and supporting ways of ensuring patient involvement at all levels.

4.1.2 The recently formed European Patients Forum will provide a useful mechanism through which to channel patient views which can enhance the EU Health Forum established in 2001 to bring together a range of European health stakeholders which should include social organisations with health related interests. These initiatives recognise the respective roles of State and non-governmental organisations in public health which need to be supported.

4.1.3 In this context it is important that individual patients or patient groups involved in such decision-making processes should be well briefed on the processes involved and the extent to which influence needs to be exerted. It is essential that mutual trust be established between those who have professional and technical expertise and those whose role it is to ensure that the public receives accurate and comprehensible information on medicines.

<sup>(1)</sup> Opinion of the EESC on the proposal of a Regulation, OJ C 61/1 of 14.3.2003.

<sup>(2)</sup> Opinion of the EESC on the proposal for a Decision OJ C 116/18 of 20.4.2001.

4.1.4 The EESC views it as critically important that the quality and availability of information to patients and the public are strengthened particularly in relation to their objectivity and availability. This was acknowledged by the Council of Ministers in the conclusion on Medicinal Products and Public Health in June 2000. To this end the EESC would strongly support the proposal for the development of a 'kite mark' to establish 'quality criteria for health-related websites' and that this should also apply to the other forms of information provision. It is essential that information should be used to inform individuals and where appropriate encourage them to seek advice from health care professionals, as the avoidance of an over or inappropriate consumption of medicines must be a priority.

4.1.5 The proposal to establish a collaborative public private partnership involving a range of contributors to inform, advise and monitor information provision is welcomed and the EESC would encourage the bringing together of pharmaceutical companies, representatives of patients, academic, social, mutual and disabled persons' organisations, scientific and health professionals which can contribute to improved patient information and health education. Such partnerships could provide essential information to governments, the EU Parliament, Commission and Council of Ministers on a range of issues pertaining to the industry and the health care of individuals.

4.1.6 The use of information dissemination to enhance public health in the Member States will be one of the important elements to enable greater harmony and promote valid collection and analyses to be carried out more effectively.

4.1.7 The EESC strongly endorses the proposal that the prohibition on advertising prescription medicines to the public should remain. The issue of advertising non-prescription medicines needs to be handled with great care to ensure the appropriate use of medicines.

4.1.8 The EESC would endorse the view that responsible self-medication is best achieved when the potential user benefits from advice from a knowledgeable health professional. Inappropriate self-medication can lead to delays in starting treatment and in some cases adverse interactions with prescribed medicines.

#### 4.2 *Relative effectiveness*

4.2.1 The EESC strongly supports the definition of 'relative effectiveness' as adopted by the Commission in relation to health-care technologies such as medicines. This comprises the

'added therapeutic value (ATV) being a composite of clinical effectiveness compared to other treatments and the cost effectiveness per se'. However, it is recognised that there might be some difficulties in Member States adopting this approach so it is important that sufficient time is allowed to encompass this effectively.

4.2.2 The EESC recognises the importance of ensuring the increasing availability of -effective (not least in terms of cost), new and safe medicines for the greatest number of people. The application of the relative effectiveness criteria in Member States will have a direct impact on prices and reimbursement that are the responsibilities of each Member State. The EESC wishes to draw attention to the impact on social care budgets which differ between Member States which prevent the prescription of the most efficacious medicine because of budgetary constraints.

4.2.3 It would be advisable to promote the exchange of experience in evaluating cost-effectiveness, in order to improve the evaluation techniques used in the various Member States.

#### 4.3 *Pharmacovigilance*

4.3.1 The EESC is in agreement that a strong pharmacovigilance system is vital and believes that existing systems must be strengthened. All health professionals involved in the prescribing or dispensing processes, as well as patients, should participate in an effective post marketing surveillance system applied to all medicines. This spontaneous reporting system should be particularly stringent for newly marketed medicines. Additionally, should the move to more rapid licensing take place it would be necessary to complement this with careful pharmacovigilance using observational studies to seek evidence of the expected safety of the medicines in question, or any unexpected toxicity as rapidly as possible.

4.3.2 Whilst randomised controlled clinical trials are the accepted way to demonstrate efficacy of medicines, they are usually of insufficient size or are conducted on patients who are unrepresentative of all potential users of the drug. These trials are therefore unable to provide evidence of potential risks, especially in vulnerable categories of patients. Thus the observational studies add a different type of information to the controlled trials, and indeed complement them. Observational studies can only rarely give information about desired effects, although they can sometimes give details of when an anticipated (good) effect did not occur.

#### 4.4 *Developing a competitive European-based industry*

4.4.1 The EESC recognises the position of the pharmaceutical industry in its contribution to the European trade balance in high technology and in meeting social and public health goals. It is a key source of highly skilled jobs. It is therefore critically important that the legislative and regulatory frameworks operate smoothly to encourage and support the industry and that EU Member States act at national level to ensure that new medicines with added therapeutic value are available to their patients as quickly as possible. It is important to promote and support research to enhance the development of new treatments.

4.4.2 Whilst the EESC endorses the key actions proposed by the Commission it is of the view that:

— it is essential to reduce the length of time that a new chemical entity spends in the development phase before licensing. The ability to pick up on adverse events after clinical use begins also needs to be faster;

— the more stringent data-protection regulations are making it very difficult to conduct the necessary observational studies to determine the safety of medicines in everyday use. Observational studies are the only practical way to identify infrequent adverse (safety) issues. They depend upon linking disparate pre-existing data sets (e.g. prescribing data, demographic data and outcome data such as hospitalisation and or death-certificate data). Personal identifiers are usually the only method to link these data sets. Recent legislation forces patient approvals to be sought for such use of personal information even where anonymisation takes place after the linkage occurs. If a significant number of individuals withhold such approval or just ignore the request, the resulting data set then contains unknown biases, which can render it much less valuable, as it is no longer representative of the parent population<sup>(1)</sup>;

— the EESC would draw attention to its previously stated view on this issue 'that there should be a systematic approach, which can be fully implemented without individual data, using only aggregated anonymous information'<sup>(2)</sup>.

4.4.3 The EESC would support the Pharmaceutical Review to improve the functioning of the Centralised and Mutual Recognition procedures in order to speed up the evaluation process and to shorten the time for the final decision to be taken. The fact that the Commission and the EMEA have already reduced the length of their own internal procedures is to be welcomed but further improvement is needed to bring new therapies to European patients in a timely manner, so that

patients receiving healthcare in Europe are not in a less favourable position than those who are receiving treatment in the US.

4.4.4 Support for the development of innovative medicines through the 6th Framework Programme for Research (FP6) with its thematic priority of research into 'Life sciences, genomics and biotechnology for health' is welcomed as a first step.

4.4.5 There would be additional benefits in moves towards reducing the time between the initial patenting of a potential medicine and submission of a request for marketing authorisation by avoiding unnecessary procedures.

4.4.6 Whilst the proposal to harmonise data protection at ten years is supported by the EESC, where additional information is provided for special sub-groups such as children, it is felt that the possibility of extending data exclusivity for one additional year could be subject to further debate.

#### 4.5 *Timing of reimbursement and pricing negotiations*

4.5.1 The EESC is in agreement that the focus should be on 'securing the most effective treatment for the patient within an effective health-care system' particularly in the light of the costs of care rising. It should be noted that pharmaceuticals account for 15 % of health budgets on average<sup>(3)</sup>. EU Member States also have an obligation to ensure that decisions on pricing and reimbursement are taken transparently in a non-discriminatory way within a precise framework<sup>(4)</sup>.

4.5.2 It must be noted that Member States have clear competence to take national measures in order to control health-care expenditures. This leads to widely divergent prices between States that will be exacerbated with enlargement. However, the EESC would want to emphasise that whatever pricing system is established it should not create a barrier to ensuring that innovative good medicines go onto the market. The Committee calls on the Commission to take action to ensure the full application of the 'Transparency' Directive (Directive 89/105/EEC).

4.5.3 Such disparities in administratively fixed prices could be detrimental to a smooth running internal market. The EESC therefore welcomes the proposal from the Commission that a 'reflection' should be launched to consider alternative ways to control national pharmaceutical-related expenditure by Member States. The EESC is in agreement that more dynamic and competitive market mechanisms could facilitate the objective of creating a more integrated market. The 'Reflection' should include a review of private and public financing of medicines, and public health.

<sup>(1)</sup> Ibid.

<sup>(2)</sup> Ibid.

<sup>(3)</sup> Benchmarking Pharmaceutical Expenditure published in 2001 by the Austrian Health Institute.

<sup>(4)</sup> Council Directive 89/105/EEC, OJ L 40 of 11.2.1989.

#### 4.5.4 Full competition for medicines neither purchased nor reimbursed by the State

4.5.4.1 The EESC feels that when a new medicine has received marketing authorisation (confirming its effectiveness, safety and quality), it should be made available to patients without unnecessary delay when the state of their health requires it. The EESC supports the possibility of making new medicines available immediately after they have received marketing authorisation.

4.5.4.2 Funding and monitoring of health expenditure in Member States might constitute a barrier to simultaneous access by patients to new medicines across the European Union. The EESC can support the replacement of direct price controls by monitoring of health expenditure and would encourage the Commission to stimulate debate on possible methods for achieving this. In this context, it should be possible to consider abandoning price controls on manufacturers for medicines that are neither publicly purchased nor reimbursed under mandatory healthcare insurance.

#### 4.6 Competitive generic market

4.6.1 The EESC would agree with the important role of generic medicines in containing health care costs, therefore assisting in improving the sustainability of financing health care, but it is important to balance the use of these medicines with the development of innovative products so that the industry remains dynamic and patients have more choice.

4.6.2 The EESC supports the establishment of a clearer Community definition of generics, and in particular the need to consider the intellectual property rights in the light of enlargement.

#### 4.7 Competitive non-prescription market

4.7.1 Whilst it is acknowledged that non-prescription medicines which can be obtained through pharmacies or through general retail outlets have the advantage of developing competitiveness in the market and the public gets greater access to those medicines without the need for a medical consultation. The EESC believes that it is important to ensure that these medicines are used under conditions of absolute safety.

4.7.2 There are inconsistencies in the products that are classified as non-prescription amongst the Member States and the EESC would endorse the proposals that greater consistency of classification decisions should be developed in line with the principles of the single market.

4.7.3 In addition the EESC would support the proposal from the Commission that the same trademark should be used for both prescription and non-prescription medicines in the Member States that are confident that this presents no risk to public health.

4.7.4 However, the EESC reiterates the concern expressed about the availability of non-prescription oral antibiotics, antivirals or anti-fungals which should be restricted to prescription only status. If such medicines are used for trivial indications, or inappropriately, there is a risk of creating wider problems of resistance that would impact in any subsequent illness particularly a more critical infection. It is therefore important that these medicines should be seen in the context of the wider public health agenda and their use controlled by prescription. It is critically important that there is accurate and easy to understand information provided to patients in this respect and that the use of such prescribed drugs are monitored and included in future research.

#### 4.8 Strengthening of the EU science base

4.8.1 The EESC acknowledges the importance of developing and sustaining a dynamic research and development base in the pharmaceutical industry that draws on the expertise contained both in the industry and allied scientific institutions.

4.8.2 The EESC supports the objective of creating virtual institutes of health to stimulate and organise health and biotechnology research in Europe to bring together those with common research interests. The EESC believes that there should be a coherent structure to bring together the knowledge and expertise with appropriate methods of dissemination if it is to retain the scientific skills of professionals and to be a serious rival in terms of R & D and innovation to the US. The 6<sup>th</sup> Framework programme for Research (FP6) is a welcome first step.

4.8.3 The EESC in a previous opinion supported the introduction of a European Centre for Disease Prevention and Control <sup>(1)</sup> in order to create a stronger science base for public health in Europe.

4.8.4 In supporting the development of research and innovation the EESC would wish to emphasise that new sources of investment must be identified. To this end the EESC welcomes the proposal to examine a number of ideas in relation to the financing of research which include venture capital, low cost loans, tax credits, guaranteed markets and the extension of patent rights and or market exclusivity. It is important that the synergy between universities, research faculties and industry is better recognised and utilised.

<sup>(1)</sup> Opinion of the EESC 'A European Centre for Disease Prevention and Control' — rapporteur Mr Bedossa — OJ C 32 of 5.2.2004.

#### 4.9 Incentives for research

4.9.1 The EESC welcomes the Directive relating to Clinical Trials <sup>(1)</sup> that stresses that the protection of patients is of paramount importance in the design of a trial. The Directive also stresses the need to simplify and harmonise the governing administrative procedures to allow for better coordination of trials within the Union. The provision to set up a European clinical trials database for the first time is also welcomed.

4.9.2 The EESC would wish to emphasise that the source of real innovation also comes from small individual companies or individuals who have a 'bright idea'. There is a risk that the complex administrative procedures within the EU and Member States or the need within larger companies to operate a selection in research projects that can be progressed simultaneously might prevent the emergence of innovative ideas from these sources. Allowance should be made to support this potential and to promote collaborations between undertakings with a view to helping the development of such ideas into new treatments that have the potential of reaching the market.

4.9.3 In comparison with the US the EU and its Member States at national level frequently focus on the need to 'avoid failure' rather than taking the risk to achieve success which might result in some failures. There is an opportunity to push out the boundaries in this respect. The EESC supports the rapid implementation of the Directive on the Legal Protection of Biotechnological Inventions by all Member States as soon as possible given that non-compliance will impede the development of the European Biotech industry.

4.9.4 The EESC also supports the adoption of the Community patent legislation which will reduce costs to each Member State.

4.9.5 The EESC would wish to emphasise that at present 40-50 % of medicines for children are not licensed for children and nor has a licence been sought for paediatric use. The EESC would wish to recommend that targeted research to assess appropriate doses of medicines for children, older people, men and women be conducted. The key issue is the appropriate safe and effective dose of the medicine for the specific circumstance.

4.9.6 The correct dosage is particularly relevant in relation to older people who might be taking a number of different medications for several indications, whilst at the same time have mild organ failure (e.g. kidney or liver) so the issue is the appropriateness of medication in relation to that being prescribed for other conditions.

<sup>(1)</sup> Directive 2001/20/EC, OJ L 121 of 1.5.2001.

4.9.7 The EESC would also wish to point out that whilst there are conditions which are currently very rare in Europe they may well be common in the developing world and that the increased rate of travel combined with global warming could cause some 'orphan <sup>(2)</sup>' diseases to become more common and difficult to contain.

#### 4.10 Medicines in an enlarged European Union

4.10.1 The EESC agrees that a major challenge will be the integration of the economies and health-care systems of the new member states into the existing Union. Most of the countries joining the Union have fewer resources to spend in their health-care sectors than existing Member States therefore the availability and affordability of pharmaceuticals in relation to their public health-care systems is of great importance. This has to be viewed in the context of rising health care costs, an ageing population and new emerging social and health care needs.

4.10.2 The challenge will also be to harmonise the intellectual property rights that could create significant differences in price levels and consequently lead to an increase in parallel imports. These occur when there are systematic price differentials between Member States. Individuals or organisations other than the market authorisation holder can then purchase a medicine in bulk in the less expensive country, import it to a more expensive country and sell it at a profit arising solely from the price differential. The EESC supports the measures proposed by the Commission to tackle this problem through a statutory requirement to inform the marketing authorisation holder, the competent authority in the Member State and the EMEA, of an intention to proceed with a parallel import in a particular Member State.

4.10.3 It is, however, noted that the legal responsibility for enforcing intellectual property rights will remain with the patent holder.

4.10.4 The EESC welcomes the steps taken by the Commission to ensure that the new member states have the opportunity for dialogue in relation to any difficulties they might experience in the implementation of the pharmaceutical legislative framework both before accession and following it.

<sup>(2)</sup> An 'orphan' disease is one which is very rare in Europe although it may be amongst the most common diseases in the world which occur largely, if not exclusively, in tropical countries with great poverty. For such diseases there is no well-developed market for competitively priced pharmaceuticals and hence little investment by the pharmaceutical industry to target these diseases. E.g. Malaria, schistosomiasis and leprosy.

#### 4.11 Member States learning from each other

4.11.1 Fundamental to progress on the development of the pharmaceutical sector in Europe is the ability to learn from each other. The EESC therefore welcomes the Commission's proposal to establish a set of EU indicators to cover the industry competitiveness and the public health objectives. The setting-up of a working group to develop these indicators is welcomed by the EESC.

4.11.2 The indicators will need to encompass the performance of the pharmaceutical product and also those related to health care provided in addition to:

- supply;
- demand and regulatory framework;
- industry output;
- macroeconomic factors.

#### 5. Conclusion

5.1 The EESC welcomes the Communication from the Commission 'to develop a stronger European-based Pharmaceutical Industry for the benefit of the patient' and supports the comprehensive programme which is set out. It is recognised that the Communication is ambitious and that it will be challenging to fulfil the objectives.

5.2 The EESC is of the view that whilst the Communication fulfils the objectives of considering the benefits to patients, moving forward on a competitive European-based industry, taking steps to strengthen the EU science base, taking account of the enlarged European Union and ensuring that Member States learn from each other, it would wish the following issues to be noted.

5.3 The EESC would wish to emphasise that the dependence on the decision-making processes in the 25 national governments make the pharmaceutical industry appear weaker in comparison to the unified approaches that are possible in the US or Japan in relation to research, innovation, marketing and pricing. It is stressed that the process begun with the G10 recommendations to reach a genuine single market should be pursued and the impact on the health care systems and public health in Member States must be checked through the proposed benchmarking exercise.

5.4 The EESC would draw attention to the range of reviews, documents and policy proposals relating to the pharmaceutical sector over the past few years and is concerned as to how

more rapid progress will be achieved as a result of the G10 recommendations, the Communication and commitments made by the Council of Ministers.

5.5 The EESC acknowledges the difficulties in achieving an integrated single market in respect of the pharmaceutical sector in view of its complexity and dependence on Member States competencies and differing systems. However, it stresses the importance of putting in place clear strategies to achieve this goal.

5.6 The EESC endorses the Commission's intention to establish performance indicators to enable the evaluation and monitoring of progress within the industry and again emphasises the importance of obtaining consistent statistical data and evidence on which to judge the progress of the programme set out in the Communication.

5.7 The EESC continues to emphasise the great importance it attaches to the protection of human health and that it should take precedence in all areas of regulation.

5.8 The EESC strongly supports the proposal for the development of a 'kite mark' to establish quality criteria for health-related websites and all other forms of information and stresses the importance of encouraging people to seek advice from health care professionals.

5.9 The EESC supports a strong pharmacovigilance system which must continue to be strengthened, and a more efficient use of epidemiological studies needs to be integrated.

5.10 The EESC believes that there is a real opportunity to develop a better coordinated approach to the research agenda with simpler and more harmonised administrative procedures. The potential for new sources of investment, which might include venture capital, low cost loans, tax credits, is welcomed and should urgently be pursued.

5.11 The EESC recommends continued dialogue and the simplification of systems to allow innovation and the sharing of knowledge both to strengthen the industry but also to sustain and develop the skills and employment capacity resulting from a competitive pharmaceutical industry.

5.12 The EESC also recommends investment by the EU and EU Member States in order to ensure that networks of excellence are established and to allow funding over a reasonably long period of time to foster innovation by providing a level of certainty and security to sustain continuity of research team work.

Brussels, 2 June 2004.

*The President*  
*of the European Economic and Social Committee*  
Roger BRIESCH

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