Opinion of the European Economic and Social Committee on the ‘Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector’

COM(2008) 666 final
(2009/C 318/14)

Rapporteur: Mr van IERSEL

On 10 December 2008 the 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 European parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: Safe, Innovative and Accessible Medicines: a Renewed Vision for the Pharmaceutical Sector’

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 9 September 2009. The rapporteur was Mr van IERSEL.

At its 456th plenary session, held on 30 September and 1 October 2009 (meeting of 30 September), the European Economic and Social Committee adopted the following opinion by 170 votes to 1 with 4 abstentions.

1. Conclusions and recommendations

1.1 The Communication (1) seeks to set a long-term agenda for progress towards a European Single Market for the pharmaceutical industry (2) which should create a sustainable environment for the pharmaceutical industry in Europe and worldwide in response to the increased needs of patients.

1.2 The EESC believes that the Communication provides an indispensable framework, containing a number of valuable objectives. It remains, however, rather cautious and ambiguous on the way this programme should be carried out.

1.3 The pharmaceutical industry depends very much on national health care and financial conditions. It also faces challenges from increased needs and expectations of populations and patients and intensifying world competition. The current crisis, together with the downsizing of budgets, will also affect the future of the pharmaceutical sector.

1.4 In the EESC’s view, these factors make it all the more urgent for the Council to draw up a comprehensive agenda to address these challenges on the basis of an agreed strategic outlook. The EU objective should be to set conditions for a sustainable home-based position and worldwide development of the European pharmaceutical industry.

1.5 A common outlook implies that the current, mainly national competences that make free access to medicines and a Single market, however desirable, still a distant reality must be progressively replaced by convergent practices and common approaches for the benefit of European patients, the industry and the whole health care chain.

1.6 In the EESC’s view national arrangements should more explicitly take the European dimension into account. The national financial and health conditions should notably take into account the huge costs and importance of future-oriented R&D and innovation in the sector.

1.7 The EESC welcomes the Innovative Medicines Initiative as part of FP7. It endorses strongly the adoption of an EC patent. It advocates a European litigation system. The functioning of the European Patent Office should be further improved.

1.8 Generic medicines are an opportunity for savings in health care. The EESC endorses the development of competitive off-patent markets. The Council should consider ways of unlocking the potential for significant savings in this field.

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(2) In 2007 the European pharmaceutical industry employed about 600,000 people, and it spent 18% of its total turnover on R&D.
1.9 Free access and affordability of medicines require a renewed discussion on the interconnected issues around huge price differences between drugs across Europe, accessibility, parallel trade and the principle of non-extraterritoriality. This discussion should also address ‘a proposal containing appropriate measures leading towards the abolition of any remaining barriers or distortion of the free movement of medicinal products …’ (1).

1.10 For the time being, the EESC is of the opinion that the Open Method of Coordination as well as a monitoring role of the Commission, best practices and transparent data, as is current practice under the Lisbon Strategy, should be introduced to promote more convergence. Worldwide figures and trends, and their impact, should be part of the data package putting challenges and opportunities for the industry in the right perspective.

2. Introduction

2.1 Owing to the divided competences of the Commission and the Member States, a comprehensive European view of the pharmaceutical sector has been lacking for a long time. The European Institutions were mainly focused on improvement of market access and regulatory affairs.

2.2 Reluctance at EU level was and is due to the exceptional position of the health sector and health care national systems and competences prevail across the board. Nonetheless, the Commission and the Member States have increasingly underlined the need for European framework conditions for well-defined health care issues.

2.3 European conditions and objectives are indispensable for a sector that is relying on long-term research and innovation-driven investments. This is all the more important because:

— the pharmaceutical sector is heavily dependent on R&D and innovative new products;

— the competition from elsewhere, including from emerging Asian countries, is increasing.

2.4 The single market needs in-depth investments. It is quite understandable that the European Court of Justice asks in several verdicts for a single market to be implemented in this sector, in particular in the interest of patients. This Single Market is seriously hampered by 27 health care systems,

2.5 As late as 1996, Commissioner Bangemann, responsible for industrial development, organised three Round Tables with all stakeholders on the European completion of the single market in pharmaceuticals. It was followed by numerous other consultations. The heterogeneous composition of the Round Tables with government representatives, pharmaceutical enterprises, and other stakeholders presents a wide variety of views and national approaches.

2.6 In response the EESC has reiterated on several occasions a number of concrete proposals. The main themes were a free movement of medicines in the EU, the need to bring pharmaceutical spending in the Member States under control, and a plea for a strong pharmaceutical industry for growth and jobs in Europe (2). Much has still to be done to make progress in these fields.

2.7 The position of the Member States is the key. The national structural and organisational characteristics of their health care systems are decisive for price and reimbursement in Europe and for access to medicines.

2.8 In spite of differences of opinion and the preservation of national competences the Council has adopted since 1965 a series of legislative measures on public health and medicinal products in order to improve conditions for patients and health care.

2.9 In 2001 it was decided to improve the structure of the debate by setting up a restricted group of interested parties, G-10 (3). In May 2002 G-10 presented fourteen general recommendations as a strategic outline for the pharmaceutical sector. In the subsequent years several recommendations were implemented.

2.10 Subsequently, a High Level Pharmaceutical Forum was established in 2005 to implement the remaining recommendations of G-10, three working groups were assigned to draw up new recommendations.

2.11 This process was concluded in October 2008, when the Forum adopted its Conclusions and Recommendations on Information to Patients, Relative Effectiveness, and Pricing and Reimbursement.

(1) See art. 9 of the Council directive 89/105 EC of 21 December 1988.
Since then the Council became more reluctant to the enlargement.


(3) G 10 was composed of five Ministers, two Commissioners and representatives of the industry.
2.12 These Conclusions and Recommendations stressed the interconnection between, on the one hand, technology and innovation within a dynamic competitive market and, on the other, quality guarantees, free access to pharmaceutical products, reliable information to patients, and effective pricing and reimbursement policies.

2.13 The Pharmaceutical Forum concludes that both the Lisbon Strategy to reinforce European competitiveness and the dynamics and challenges of the pharmaceutical sector worldwide require at this very moment an in-depth approach and a mid- and long-term view on the sector.

2.14 For the first time FP7 has set up a common research agenda for the pharmaceutical industry. It includes a large number of innovative pharmaceutical projects that stimulate existing and potential international research networks (1).

2.15 Meanwhile, the effects of globalisation are becoming palpable. Taking into account impressive R&D achievements in the US and in China and other emerging economies, the innovative exposure of European companies in this sector will in the end be decisive for a European industry.

2.16 Owing to the current economic crisis the world will look different afterwards. The state of the economy, together with the downsizing of national budgets, as well as the reinforced position of other global players in Asia, will affect competitive conditions. These factors must be seriously taken into account in any future policy towards the health sector and the industry.

2.17 The EESC concludes that during the last decade networks and exchanges have intensified which, to a certain extent, have resulted in a convergence of views among many stakeholders. Despite this progress black spots remain owing to differences in legislation and health systems. Free access to pharmaceutical products is limited and there is no single market for the industry.

3. The Commission’s views

3.1 The Commission published in December 2008 a strategic Communication on the pharmaceutical sector that defines principles and objectives, and the prospects for the sector over a long period of time, as well as worldwide challenges.

3.2 The Communication provides the framework for the legislative proposals in the total package of December 2008, and for the future.

3.3 A new element is the major emphasis on external aspects, such as counterfeiting, trade, new illnesses as well as the increasing significance of emerging economies.

3.4 The Communication identifies three issues, covered by five legislative proposals accompanying the Communication: counterfeiting of medicinal products, pharmacovigilance, and information for patients (2).

3.5 Once again, the paramount significance of the pharmaceutical industry for Europe in terms of R&D, growth and jobs, and public health is underlined.

3.6 However, Europe is facing major health, scientific and economic challenges to maintain a viable and sustainable pharmaceutical industry:

— Europe continues to lose ground to the US and Asia in R&D and innovation;

— within the EU inequalities in availability and affordability of medicines persist;

— increasing international division of labour, including R&D, clinical trials manufacturing, and marketing;

— the need for further scientific pioneering to respond to unmet public health challenges as well as to open new markets for medicines produced in the EU.

3.7 The Commission considers it high time to make further progress towards improving the functioning of the single market for pharmaceuticals in order to stabilise and reinforce Europe’s position worldwide.

3.8 To that end 25 objectives are defined, concerning (a) a single and sustainable market in pharmaceuticals, (b) taking on the opportunities and challenges of globalisation, and (c) strengthening the environment for science and innovation.

(1) In comments concerning Communications of the Commission on research and competitiveness in the pharmaceutical industry the EESC has continuously underlined the crucial significance of (basic) research in this sector. See OJ C 14 of 16.1.2001, OJ C 214 of 30.9.2003 and OJ C 110 of 30.4.2004.

This Communication presents a coherent picture of the domestic and worldwide challenges and desirable approaches in an overarching framework that should set a long-term agenda in this sector.

4. General observations

4.1 The EESC endorses the need for an overarching approach concerning the European pharmaceutical sector in a worldwide perspective.

4.2 The Communication is presented as a ‘Renewed Vision’. However desirable and in spite of a broad consultation of many stakeholders, the result is somewhat disappointing as it is lacking an overall analysis of shortcomings in the common market as well as a pro-active approach in terms of policy recommendations in the light of patients’ and industrial interests.

4.3 Europe has been losing ground in pharmaceutical innovation. The globalisation of the sector gives rise to new opportunities and new challenges. The lack of free access to medicines in Europe, and the need for scientific breakthroughs to respond to medical progress as well as to global public health challenges are rightly put together in the same picture. It remains unclear what actions should be taken by Member States and in the EU in response to these challenges.

4.4 In the EESC’s view there is an urgent need to improve the functioning of a sustainable Single market in pharmaceuticals which is a pre-condition for maintaining a profitable, highly innovative pharmaceutical sector in Europe to respond to the increased needs of the population as well as worldwide challenges.

4.5 The Communication offers an appropriate framework for regulatory cooperation and negotiations with an increasing number of third countries, such as the US, Japan, Canada, Russia, India and China. Through cooperation and negotiations with third countries a sustainable perspective will be created for European exports.

4.6 In that international context a well functioning single market is a prerequisite. Market fragmentation continues either as result of disparities in national pricing and reimbursement schemes or (new) regulatory burdens, shortcomings in implementation of Community legislation, access inequalities, and a lack of commercial interest in national markets which are economically less attractive.

4.7 Moreover, in a rather short period of time the EU has grown to 27 Member States each with its own and, thus, additional specific features, not least because of the increased diversity of markets and patient needs. This illustrates the complexity of the overall European picture.

4.7.1 An example of this complexity is the affordability of medicines that is highly dependent on the various national social security systems and the degree to which people are insured. In most systems, the social security institutions or their associations negotiate the price of prescription-only medicines with manufacturers, so that they can then be supplied at a reasonable price, albeit with a small excess to be paid by the insured person.

4.8 The relationship between innovation costs and turnover in the sector has a big impact. Research and innovation can only flourish on condition that the industry is competitive and that, thus, the European market functions satisfactorily.

4.9 If divergence in administrative procedures and approaches persists, the sector will continuously suffer from fragmentation, overlap, excessive innovation costs, and, thus, from disadvantages vis-à-vis industries that are able to enjoy advantages on a continental scale, such as the US and China.

4.10 Although elsewhere in the world large markets on a continental scale are partly influenced by regional differences, the situation is not comparable with the fragmentation in Europe.

4.11 An additional problem is that the productivity of pharmaceutical R&D spending has been declining over recent years owing to a combination of several complex factors.

4.11.1 The biotech revolution, while promising many new advances, has been costly for industry as R&D and applied technology have not yet been translated into a mature pipeline of products. Tackling new disease implies more costly development of products.

4.11.2 The cost of bringing new products to the market has increased, in part due to the need for extensive and expensive clinical trials. The regulatory requirements on clinical development have also increased whilst research and development have moved towards more complex diseases and therapeutic areas such as cancer, Alzheimer, and others.

4.11.3 Medical innovation is currently primarily seen as a cost factor for national health budgets rather than as a driver to innovation for the patients’ well-being. Illustrative are national pricing and reimbursement policies which do not provide for higher rewards for innovative products compared to older ones in certain diseases areas (e.g. therapeutic reference pricing).
4.12 This development in Europe has consequences vis-à-vis competitors. While the Regulatory Authorities in the US are on average stricter in approving market authorisation than in the EU, the US market environment is more attractive to R&D investments, because it rewards innovation more than most European markets do.

4.13 Asian countries such as China and India, whose markets grow by more than 15% per year on average, are likely to attract a significant share of international R&D investments once intellectual property protection standards are effectively enforced in these countries.

4.14 For further progress in this area a new balance has to be struck between the remaining national competences and European (legal) mechanisms and procedures, and market conditions which pave the way for a viable and strong European pharmaceutical sector.

5. Meeting the future

5.1 The EESC is of the opinion that the conjunction of the current economic crisis, the preparation for a revamped Lisbon Strategy in 2010, and worldwide challenges are for the forthcoming Commission an appropriate starting point for renewal and progress.

5.2 The Lisbon Strategy, which entails the fine-tuning of national and Community competences and a clearer role for the Commission, can provide a helpful framework and methodology for the pharmaceutical industry.

5.3 In 2008 the Commission launched the Innovative Medicines Initiative (IMI)(1) as part of FP7. The EESC welcomes this strategic agenda, that is effectively working towards solutions to research challenges via public-private partnerships – universities, research institutes, SMEs, hospitals, patient organisations and regulators – aiming at removing bottlenecks in science and skills in order to speed up drug development for future health needs.

5.4 In competitive research, patents and guaranteed intellectual property protection in the pharmaceutical sector are crucial as incentives to innovate and to address current and emerging health problems and the long life cycle of products (including long development periods).

5.5 The EESC has taken note of the Interim Report of November 2008 on a Sector Inquiry into pharmaceuticals. The EESC strongly endorses the recommended adoption of an EC patent and the setting up of a European litigation system which will streamline processes and save costs, as opposed to 27 litigation procedures on the basis of different legislations.

5.6 Notwithstanding the worldwide reputation of the European Patent Office, the EESC considers that its functioning can be improved.

5.7 Generic medicines which are copies of originator medicines once patents have expired, are substantially cheaper to produce and to market than originator medicines. The EESC endorses the development of competitive off-patent markets.

5.8 The EESC stresses the need for more efficiency and competition on the European generic market. The EESC calls on the Commission and Member States to consider ways of unlocking the potential for significant savings for patients and health care systems.

5.9 As regards free access and affordability of medicines, the EESC calls for a renewed discussion involving the Commission, governments, and stakeholders on interconnected issues such as huge price differences between drugs across Europe, accessibility, parallel trade and the principle of non extra-territoriality.

5.10 For guidance the EESC points to a consecutive number of statements of the G10, Recommendation 6, the High Level Pharmaceutical Forum, Recommendation 9.2, and the Final Progress Report of this Forum(2).

5.11 The objective of such a discussion should be the definition of a common vision on the need for free access and affordability for patients, on the creation of a single market, on the predictability of governments' behaviour and actions in this field as well as on the need for a sustainable environment for R&D and innovation.

5.12 Domestic and worldwide challenges are interconnected:

—— the position of the European pharmaceutical industry at global level will depend on its home-based position in Europe;

—— diseases on a global scale, and the worldwide circulation of pharmaceutical products from developed and emerging economies which will also affect European markets;

—— a sustainable home-based position of the industry must be beneficial to patients as a result of discussion platforms relating to pharmaceutical products, illnesses, and changing attitudes among consumers of these products in Europe.

(1) The IMI Strategic Research Agenda is the roadmap for the rapid implementation of IMI, the focus being on four pillars: Safety, Efficacy, Knowledge Management, and Education and Training.

(2) See p. 85 of the Final Progress Report.
5.13 In support of the renewed discussion the Commission should present up-to-date EU figures on market developments, job creation and R&D budgets in the sector. There is also a strong need for comparable worldwide figures.

5.14 Worldwide figures and trends must also cover the extension of R&D activities of European companies in large emerging markets, which will undoubtedly take place along with the growth of markets in China and India. This benefit of globalisation is another compelling argument to develop the European Single Market as a sustainable basis for R&D and innovation.

5.15 Fair trade and the interests of patients require that imports from low-income countries must effectively be subject to good manufacturing practices. Counterfeit medicines shall be prohibited. The risk of Internet sales of counterfeit medicines shall be diminished by effective control of medicines that are sent by mail.

5.16 The EESC is of the opinion that in order to get closer to a Single Market in this sector, the Open Method of Coordination as well as a monitoring role for the Commission, as is current practice under the Lisbon Strategy, should be introduced.

5.17 With a view to achieving greater transparency, the Commission should publish best practices, and examine and highlight debates and developments in Member States, related to free access and affordability of medicines as well as to legal conditions for R&D, innovation and the pharmaceutical industry. The results of these examinations should be the basis for decision-making by the Council.

Brussels, 30 September 2009.

The President
of the European Economic and Social Committee
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