



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 23 September 2003**

**12885/03**

**ECO 181  
SAN 190  
COMPET 46  
IND 125  
MI 220  
RECH 153  
ENV 468  
AGRI 285  
SOC 357**

**NOTE**

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From : General secretariat

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Subject : Outcome of proceedings of the Competitiveness Council on 22 September 2003  
- Council conclusions and resolution (Industry and Research)

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At its session of 22 September 2003 the Council of the European Union adopted the following Council Conclusions and Resolution in the areas of Industrial and Research Policies:

- Annex I: Council conclusions on "Reinforcing the competitiveness of the European-based pharmaceutical industry".
- Annex II: Council conclusions on "Life sciences and biotechnology - a strategy for Europe".
- Annex III: Council resolution on "Investing in research for European growth and competitiveness".

The texts set out in Annexes I and III will be published in the Official Journal.

**COUNCIL CONCLUSIONS OF 22 SEPTEMBER 2003 ON  
REINFORCING THE COMPETITIVENESS OF THE EUROPEAN-BASED  
PHARMACEUTICAL INDUSTRY**

**THE COUNCIL:**

**RECOGNISING** that the European-based pharmaceutical industry plays a vital role in both the industrial and health sectors, as well as in the science base;

**WELCOMES** the response given by the Commission to the report of the "G10 High Level Group on innovation and the provision of medicines" in its Communication on "A stronger European-based pharmaceutical Industry for the benefit of the patient"<sup>1</sup>;

**REAFFIRMS** the need for a balance between competitiveness and public health policies, while fully respecting the Community and national competencies involved;

**UNDERLINES** the need to reinforce the competitiveness of the European-based pharmaceutical industry vis-à-vis its competitors, particularly by enhancing Europe's attractiveness as a location for innovative high tech industry and for maintaining a high quality science base; this should be accompanied by measures to facilitate the development of competitive generic and non-prescription sectors in the EU;

**RECOGNISES** that establishing the framework for a sustainable improvement of the competitiveness of the pharmaceutical industry requires action to be taken at both national and EU levels;

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<sup>1</sup> Doc. 11165/03 ECO 147 SAN 152 COMPET 38 IND 103 MI 167 RECH 119.

**NOTES** that the industrial landscape in the European pharmaceutical sector is made up of complementary relations between big and small/medium enterprises spread over all the regions in Europe and **UNDERLINES** that this interrelationship should be developed and enhanced;

**HIGHLIGHTS** the importance of stimulating new and more integrated forms of co-operation, including public-private partnerships, in Europe among governments, academia, scientific institutions, pharmaceutical and biotechnology companies to improve and speed up the transfer of scientific knowledge and the availability of innovative medicines;

**WELCOMES :**

- the benchmarking exercises proposed by the Commission on both health and competitiveness issues as a guide to policy-making over time, and **UNDERLINES** in this context that new developments, such as the enlargement of the European Union, should be duly taken into account in the collection of data;
- the concept behind the European Virtual Institutes of Health, outlined by the Commission, in order to promote clinical, pharmacological and pharmaceutical research, including research on medicines with smaller markets, through linking centres of fundamental and clinical research into a European network of excellence;

**INVITES** Member States to :

- actively participate in the implementation of the key actions set out in the Commission's communication, in particular benchmarking, by providing appropriate information on legislative and non-legislative measures that could have an impact on the pharmaceutical sector;
- consider the Commission's suggested implementing actions for:
  - (a) competition concerning authorised medicines that are neither purchased nor reimbursed by the State;
  - (b) the rapid launch of medicines on the market after granting a marketing authorisation;

**INVITES** the Commission to:

- organise an EU-wide reflection together with all interested Member States and stakeholders on different approaches to pricing and reimbursement for pharmaceutical products, exploring the scope of more competitive and dynamic market mechanisms, aimed at ensuring the equitable and rapid access of patients throughout the EU to medicines, in order to improve the integration of the European market in this field, while respecting Member States' competencies and the differences in their health care systems, including the assessment of the added therapeutic value;
- report regularly to the Council, on the state of competitiveness of the pharmaceutical sector on the basis of the results of the benchmarking exercises on competitiveness and public health and of information supplied by Member States.

**COUNCIL CONCLUSIONS OF 22 SEPTEMBER 2003 ON  
LIFE SCIENCES AND BIOTECHNOLOGY – A STRATEGY FOR EUROPE**

**THE COUNCIL:**

**RECALLING** that the European biotechnology strategy aims at facilitating the comprehensive and responsible development of biotechnology applications as an important step towards a competitive knowledge-based economy;

**RECOGNISING** the important role that biotechnology, as an enabling technology, plays in many different fields, and thus its significance for the overall competitiveness of European industry;

**WELCOMES** the Commission's first progress report<sup>1</sup> on the implementation of the European biotechnology strategy and agrees with the broad lines of its analysis; in this context **RECALLS** the importance of an integrated approach addressing all the complex and multifaceted societal and economic issues involved;

**STRESSES** the need for significant efforts to be made to move from the conceptual and planning stage to the implementation of the biotechnology strategy and of the roadmap contained in the Council Conclusions of 26 November 2002<sup>2</sup> in order to contribute effectively to the achievement of the EU competitiveness objectives set by the Lisbon European Council;

**UNDERLINES** the need to encourage overall coherence in policy making and to envisage, at EU level, the development of appropriate means for closer cooperation among Member States together with the Commission, in implementing the biotechnology strategy;

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<sup>1</sup> Doc. 7473/03 RECH 37, ENV 163, CONSOM 24, SAN 46, DEVGEN 31, MI 56, IND 39, AGRI 72, SOC 129, RELEX 104, EDUC 46, AG 9

<sup>2</sup> See OJ C 39 of 18.02.2003, p. 9.

**ENCOURAGES** Member States and the Commission to step up their co-operation and to regularly exchange information on progress made in order to advance in the priority areas for future action already identified and, in particular, to improve conditions for access to finance for biotechnology companies and to complete and implement the general regulatory framework;

**AWAITS** with interest the results of the Conference on life sciences and biotechnology to be held in Rome on 21-22 November, as a source of possible further input in the process of implementing the Action Plan and the roadmap;

**INVITES** the Commission to assess the progress achieved in this area in its next report.

**COUNCIL RESOLUTION OF 22 SEPTEMBER 2003 ON INVESTING IN  
RESEARCH FOR EUROPEAN GROWTH AND COMPETITIVENESS**

**THE COUNCIL:**

**RECALLING** the conclusions of the Lisbon 2000, Barcelona 2002 and Brussels 2003 European Councils, which respectively;

- set a strategic goal for the European Union to become the most competitive knowledge-based society by 2010;
- agreed that overall spending on R&D in the Union should be increased with the aim of approaching 3% of GDP by 2010 and that two thirds of this investment should come from the private sector;
- urged Member States to take concrete action on the basis of the Commission's forthcoming R&D Action Plan, encouraged Member States to speed up the implementation of the European Charter for Small Enterprises and called for the momentum behind the European Research Area (ERA) to be maintained and strengthened by the application of the open method of co-ordination in areas such as action pursuing the 3% of GDP objective for RTD investment or developing human resources in science and technology;

the Commission Communications "Towards a European Research Area"<sup>1</sup>, "Making ERA a reality"<sup>2</sup> and "More research for Europe: Towards 3% of GDP"<sup>3</sup>, and the Council Resolutions and Conclusions on ERA, in particular the Conclusions of 26 November 2002 on progress made in the development of the European Research Area and on providing it with new momentum<sup>4</sup>;

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<sup>1</sup> Doc 5643/00 RECH 2 ATO 6

<sup>2</sup> Doc 12214/00 RECH 95 ATO 60

<sup>3</sup> Doc 12044/02 RECH 146

<sup>4</sup> Doc 14913/02 RECH 186

**WELCOMES** the Commission's Communication "Investing in research: an action plan for Europe"<sup>1</sup>, and **ENDORSES** the main message of this communication which calls for a comprehensive and coherent range of actions to increase investments in research and close the gap with Europe's main competitors;

**REAFFIRMS** that investing in research and technological development and stimulating innovation and transfer of knowledge is essential to increasing European competitiveness and to the strategy set by the Lisbon European Council for Europe's economic, social and environmental development and that there is a particular need to stimulate and improve conditions for more private investment for research and innovation;

**RECOGNISES** that :

- investment in R&D and innovation will contribute to stimulating growth and employment, taking into account the Communication of the Commission to the Council and to the European Parliament on 27 November 2002 ("Strengthening the coordination of budgetary policies")<sup>2</sup> and the conclusions of the European Council of 20/21 March 2003, the Commission communication of 7 July 2003 ("An initiative for growth: investing in Trans European Networks and major R&D projects")<sup>3</sup>, the Council conclusions of 15 July 2003 on a European action for growth<sup>4</sup> and the ongoing discussions on these subjects;
- scientific and technological excellence and quality of research remain basic criteria for increasing and attracting investment in R&D and innovation;

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<sup>1</sup> Doc. 8860/03 RECH 75 + ADD 1.

<sup>2</sup> Doc 14997/02 UEM 62

<sup>3</sup> Doc 11343/03 ECOFIN 216 FIN 321 ECO 153 TRANS 187 ENER 217 RECH 121

<sup>4</sup> Doc 11463/03 PV/CONS 43 ECOFIN 222 Annex I

- fundamental research, a broad and dynamic knowledge base, sufficient and high-quality human resources, research infrastructures and mechanisms for the efficient transfer of technology are crucial for the sustainable development of the knowledge based society;
- broad policy mixes, adapted to the respective national and regional contexts, combining financial incentives and measures to improve framework conditions, are necessary to stimulate private investment in R&D, taking into account the specific needs of SMEs, in particular new innovative SMEs and spin-off firms, as well as those of larger firms;
- a supportive policy for the further development of R&D strategies and cross-border partnerships of the European Regions, taking into account the needs of SMEs, is essential for attaining the 3% objective;
- SMEs could play an important role in raising the level of expenditure in research and innovation, as well as in fostering employment;
- the innovative and more effective use of various public financing instruments at EU and national levels, and facilitating and promoting the use of the Structural Funds in support of R&D, are key factors for raising the level of expenditure in research and innovation;
- simplification and modernisation of State Aid rules can facilitate Member States' efforts to reorient state aid expenditure towards objectives of common interest, such as R&D and SMEs
- efforts should be continued in this context to achieve closer linkage with other European cooperation initiatives such as COST, Eureka and ESF;

**INVITES** Member States, Acceding States and the Commission to :

- apply the open method of co-ordination building upon the guidelines set out by the European Council and the Council to support the implementation of the Action Plan and the achievement of the 3% objective, using, on a voluntary basis, freely chosen national qualitative and/or quantitative targets;

- use CREST as an operational interface to define and oversee the implementation of the open method of co-ordination in respect of the 3% objective, with a view to it becoming rapidly operational, recognising that the work of CREST in this respect will need active links with other ongoing actions to strengthen competitiveness;
- develop the training of researchers, promote and diversify career opportunities, and create incentives for researchers in Europe aimed at attracting and retaining high level researchers in the European Union, as well as increase mobility, by the removal of persistent obstacles to it, and in particular mobility between public and private sectors;
- enhance access to equity and debt financing for research and innovation through a range of measures giving particular attention to the needs of SMEs in new as well as traditional sectors and of new innovative SMEs and spin-off firms;
- to develop a European risk capital/venture capital market, as well as to increase complementarity between EIB and EIF initiatives and national initiatives, with specific regard to the needs of SMEs;
- promote a supportive environment for the development and deployment of new technologies and improve the social, fiscal and administrative framework conditions in order to make the European Union more attractive for private investment and stimulate the creation and growth of high-tech enterprises;
- encourage and develop new initiatives aimed at intensifying co-operation between industry and public research, enhancing in such a way the efficiency of technology transfer and transnational public private links, for example by the promotion of centres and networks of excellence, research infrastructures and industrial clusters;
- examine the possibility of using to a greater extent structural funds to support research, development and innovation, bearing in mind the role of these funds to promote social and economic cohesion, and taking into account the specific needs and potential of different regions, including those of acceding States;
- encourage entrepreneurship among students and researchers;

- promote intellectual property right (IPR) awareness and training activities targeted in particular at public research organisations and SMEs;

**INVITES** the Commission to :

- pursue its ongoing initiatives to simplify and modernise State Aid rules and procedures, considering the new relationships between R&D and production processes, taking into account a more modern and coherent definition of R&D activities and the particular needs of newly developed innovative companies;
- to support, in consultation with the Member States, the setting up of European Technology Platforms on a limited number of key technologies as a means to foster effective public-private partnership among the research community, industry and SME associations, financial institutions, users and policy makers in order to develop a strategic agenda for leading technologies and mobilise the research and innovation efforts;
- in the context of developing a strategic approach to growth and competitiveness, report annually to the Council from 2004 onwards on the progress achieved in reaching the 3% objective, on the implementation of the Action Plan, and on the application of the open method of co-ordination, identifying remaining obstacles and problems and, where appropriate, new actions needed.

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