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(Information)

COUNCIL

COUNCIL CONCLUSIONS

of 22 September 2003

on reinforcing the competitiveness of the European-based pharmaceutical industry

(2003/C 250/01)

THE COUNCIL OF THE EUROPEAN UNION,

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' ⁽¹⁾;

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;

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 inter-relationship should be developed and enhanced;

HIGHLIGHTS the importance of stimulating new and more integrated forms of cooperation, 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

⁽¹⁾ Document 11165/03 ECO 147 SAN 152 COMPET 38 IND 103 MI 167 RECH 119.

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 RESOLUTION

of 22 September 2003

on investing in research for European growth and competitiveness

(2003/C 250/02)

THE COUNCIL OF THE EUROPEAN UNION,

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 coordination 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' ⁽¹⁾, 'Making ERA a reality' ⁽²⁾ and 'More research for Europe: Towards 3 % of GDP' ⁽³⁾, 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 ⁽⁴⁾;

WELCOMES the Commission's Communication 'Investing in research: an action plan for Europe' ⁽⁵⁾, 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') ⁽⁶⁾ 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') ⁽⁷⁾, the Council conclusions of 15 July 2003 on a European action for growth ⁽⁸⁾ 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,
- 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,

⁽¹⁾ Document 5643/00 RECH 2 ATO 6.

⁽²⁾ Document 12214/00 RECH 95 ATO 60.

⁽³⁾ Document 12044/02 RECH 146.

⁽⁴⁾ Document 14913/02 RECH 186.

⁽⁵⁾ Document 8860/03 RECH 75 + ADD 1.

⁽⁶⁾ Document 14997/02 UEM 62.

⁽⁷⁾ Document 11343/03 ECOFIN 216 FIN 321 ECO 153 TRANS 187 ENER 217 RECH 121.

⁽⁸⁾ Document 11463/03 PV/CONS 43 ECOFIN 222 Annex I.