5. ENDORSES:

— the various initiatives announced in the Communication in order to increase transparency and trust in relation to the placing on the market and putting into use of medical devices;

— the working programmes attached to the Communication intended to improve implementation, as presented by the Commission, in particular in relation to market surveillance, Notified Bodies, clinical evaluation, and regulatory clarification;

— the Commission’s intention to carry out within 5 years a review of the impact of the working programmes announced in the Communication;

6. INVITES the Member States to actively engage in the reporting of information as requested by the Directive 93/42/EEC on medical devices in relation to the consultation mechanisms foreseen in those cases where medical devices contain medicinal products or human blood derivatives, clinical investigation and vigilance, allowing complete and consistent data to be made available for analysis in conformity with the provisions of the Directive:

7. INVITES THE COMMISSION AND THE MEMBER STATES:

— to set up and maintain the European Database for Medical Devices and, as a basis for the database, to start implementation of the Global Medical Devices Nomenclature;

— to strengthen coordination between the Commission and the national authorities in charge of implementing the directives in order to ensure a consistent and coherent interpretation and implementation of the directives and to achieve greater efficiency in the interest of protecting public health.

COUNCIL RESOLUTION

of 2 December 2003

on pharmaceuticals and public Health challenges — focusing on the patients

(2004/C 20/02)

THE COUNCIL OF THE EUROPEAN UNION

1. RECALLS the Council Conclusions on Medicinal Products and Public Health of 29 June 2000 (1), which stress the need for greater actions in the area of added therapeutic value, rational use of medicines and information to patients;

2. CONSIDERS that the 14 recommendations of the ‘G10 High Level Group on innovation and provision of medicines’, contained in its Report of March 2002, are designed to contribute to both industrial competitiveness and public health goals and HIGHLIGHTS in particular the recommendations that call for better information to patients and the need for stronger systems for pharmacovigilance and relative effectiveness within Member States;

3. WELCOMES the Commission communication entitled ‘A stronger European based pharmaceutical Industry for the benefit of the patient’ in response to the above-mentioned 14 recommendations of the G10 Medicines Group and

4. RECALLS the Council Conclusions of 22 September 2003 on ‘Reinforcing the competitiveness of the European-based pharmaceutical industry’ (2); REAFFIRMS the need for a balance between competitiveness and public health policies; and RECOGNISES the contribution and importance of a strong and competitive pharmaceutical industry in Europe to the improvement of public health;

5. RECALLS the common positions on the review of the Community legislation on pharmaceuticals adopted by the Council on 29 September 2003, and the importance of the review for achieving some of the goals set out in the G10 recommendations;

6. STRESSES the importance of monitoring the impact of EU enlargement for the health systems in the Member States and Acceding States, especially due to free movement of people and products, and NOTES in this context the Declaration of the Ministers of Health of the Acceding Countries signed in Milan on 5 September 2003;


7. UNDERLINES that the patients must be the focus of pharmaceutical policies and that, therefore, emphasis should, in particular, be on:

a) providing medicines needed to treat otherwise incurable diseases as well as more efficacious, safer and higher quality medicines;

b) ensuring better and more accessible information to patients, in order to promote the rational use of medicines;

c) reinforcing the systems for pharmacovigilance within Member States;

d) ensuring availability and affordability of medicines to all patients, thereby respecting the competencies of the Member States;

8. RECOGNISES that in order to respond to the public health challenges, action is required at both national and EU level while fully respecting the national and Community competencies; and AGREES that the objectives outlined in this Resolution shall be achieved by making the best possible use of available resources and means;

9. HIGHLIGHTS the increasing expenditure on medicines, whilst recognising Member States' competence to manage expenditure on health care systems, including on medicines, in accordance with national priorities and public spending limits, inter alia by promoting rational use of medicines and the use of generics;

10. SUPPORTS the development of greater coherence between public health needs and research activities at European level, and STRESSES that the concept of European Virtual Institutes of Health should be explored further in this regard as a way of co-ordinating research, while noting the importance of considering existing and proposed European structures to prevent and control diseases;

11. INVITES the Commission and the Member States to promote scientific and technological research on:

— medicines for diseases that otherwise cannot be treated effectively by developing new and more effective policies to facilitate the co-operation of public and private organisations with academia and other research institutions as well as to better bridge basic and applied research, and

— medicines needed for treating diseases of developing countries, particularly in Africa;

12. CALLS on the Commission and the Member States to co-operate in the development of an EU system of sharing available data on medicines marketed in the Member States, including exploration of ways to harmonise the collection of key data at national level. This should involve the national medicines agencies and be undertaken in collaboration with the EMEA as a possible focal point for such a system, and should be integrated with its on-going telematics work;

13. WELCOMES the EU telematic strategy to underpin the regulatory process with more effective use of existing IT resources and ENCOURAGES the Commission and the Member States, through the EMEA and the National Medicines Agencies, to implement this strategy as quickly as possible and, in particular, to establish the EuroPharm database to improve the quality and availability of product information on all medicines available in Europe;

14. ENCOURAGES the Member States to reflect on ways to improve the assessment of relative effectiveness in their decision making on the reimbursement of medicines in the interest of creating greater certainty and reliability for stakeholders. Any such decision will have to be carried out within the framework of the different national health care systems;

15. WELCOMES the Commission's project to facilitate an exchange of information in the area of relative effectiveness between Member States, and CALLS upon the Commission to develop mechanisms for Member States to generate and share this information while recognising that the issue of relative effectiveness must remain separate from the authorisation process. This exercise should be supported by better and more available comparative data;

16. CALLS on the Commission and the Member States to work collaboratively to strengthen the collection and dissemination of data that can enable the evaluation of methods for establishing the cost effectiveness of medicines, as well as of their effectiveness in relation to other treatments in Europe. In particular, consideration should be given to ways to communicate this information to health professionals and to patients;

17. INVITES the Commission to explore with the Member States, through the relevant national and European competent authorities, the possibility of setting up of a European Medicines Information System for patients and health professionals with the objective of providing information on medicines and related conditions, that is of high quality, objective, transparent, comprehensive, reliable and up-to-date. This could involve:
— extracting and using existing information within the Member States from national medicines agencies, and suppliers such as patient groups or professional bodies;

— consideration of ways to tailor this information to specific audiences, such as health professionals, patients and the general public; and

— making use of existing initiatives such as the development of a European Health Portal;

18. WELCOMES the Commission’s initiatives to explore the feasibility of actions to evaluate the quality of existing non promotional information provided to patients and to ensure quality in the provision of non promotional information to the public through internet sites. The Commission should ensure that this builds on existing European initiatives in e-health, such as the development of quality criteria for internet websites;

19. CALLS for support of the work and participation of patients’ groups in order to ensure that patients’ needs in the pharmaceutical sector are duly taken into account in the development of policy at European level. This is important as the needs of patients are the focus of pharmaceutical policies both at Community and national level;

20. INVITES the Commission to ensure in its proposed benchmarking exercise a balance between industrial, public health and social policies. To this end consideration should also be given to the role of industry, governments, health professionals and users of medicines when assessing the performance of the pharmaceutical sector;

21. CALLS on the Commission, the Member States and the EMEA, each within their competencies, to continue to develop and speed up decision-making procedures to make possible the immediate use of new medicines that are of major public health importance, such as life-saving medicines and medicines for illnesses for which there is a high probability of short term lethal outcome;

22. CALLS on the Commission to come forward with a set of incentives, regulatory measures and other supporting measures to encourage the development and marketing of paediatric medicines.