

“HEALTH IN EUROPE”

Paris Conference – 13/14 April 2005

Paris, 14 April 2005

PROTECTING THE HEALTH OF EUROPEAN CITIZENS

Summary of the discussions on proposals made by the Presidency And France

Health Ministers of the 25 countries of the European Union have met in Paris on 13th and 14th April, together with the Commissioner in charge of health and consumer protection, at the invitation of the health Minister of Luxembourg and the Minister for solidarity, health and family affairs of France.

At this occasion, Ministers have agreed on the need to strengthen common efforts to further promote a high level of health protection for all the citizens of Europe.

Ministers, following a detailed discussion and exchanges of views, have taken note that all of the countries of the European Union face common health challenges and it is in everybody's interests to respond actively to these challenges in a co-ordinated manner in accordance with the principles of the Treaty.

Ministers also noted the increased scale and complexity of the challenges to health protection at the European level, as shown by the more recent alerts and crises.

Ministers noted the significant development and improvement in public health protection at the European level, as evidenced by :

- regulations on blood products and human cells
- the autorisation and surveillance of pharmaceuticals
- measures to counter tobacco addiction, including the European anti smoking campaign "Help"
- disease surveillance and control, through the setting up of a European Centre in Stockholm

These improvements show the potentials for Europe to contribute to the development of public health in the future. The proposed new EU Constitutional Treaty contains proposals to develop these competencies in order to further improve the level of public health protection at the European level. One of the major contributions that the European Institutions can make to protecting and promoting health is to facilitate co-operation between the Member States, respecting the Member States' responsibilities for organising and managing their health systems.

Following these discussions, the Ministers have agreed to further intensify actions and efforts to protect the health of European citizens. Ministers held detailed discussions on a number of concrete proposals made by the Presidency and France and agreed to continue discussions in the more formal Council setting. They

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discussed closer co-operation in three practical fields, which concern directly the health of the European citizens : cancer, hiv/aids, influenza pandemic.

In these three fields, which have been unanimously considered as priorities, Ministers have heard presentations by European experts who have outlined potential solutions which could rapidly allow a stronger co-operation between the 25 Member States, for the benefit of the citizens of Europe.

In the field of cancer, measures proposed by experts would lead to set up an "Alliance against cancer", which will extend to better co-ordination of the national structures for research and spread of guidelines and protocols for diagnoses and treatment as well as exchange best practices.

In the field of hiv/aids, Ministers wish to strengthen the co-ordination of clinical trials in the continuing search for a vaccine, in the context of a comprehensive global response.

Finally, the Ministers have wished to make the building of a higher level of health protection as one of the priorities of the Union. The risk of pandemics makes this measure necessary. It could include reinforcing the health alerts at European level and the co-ordination of national decisions on response to crises, but also the continuation of initiatives for the development and production of vaccines.

In these three fields the Ministers have stressed the necessity to take full account of all aspects of prevention, treatment and research in combating the challenges, by using existing tools in order to avoid duplication of efforts.

They have issued an appeal to reinforce health in Europe by building on the work of the conference. Finally they wished to show their determination to use advances in scientific knowledge to improve co-operation between Member States and at European level.

A 25-nation strong Europe will be stronger in building a Europe that discovers new therapies, that shares current best practices for the benefits of the largest number of people, and that serves as protection against current or future epidemiological threats.

The Presidency and the Commission should ensure the follow up to these proposals.

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Proposals made by the Luxembourg Presidency and France

I. Setting up an “Alliance against cancer”

Cancer is the second biggest cause of mortality in Europe and accounts for four out of ten deaths in the 35-65 age groups. In 2004, 2 millions of new cancer cases have been diagnosed and 1.2 million deaths have been monitored in the 25 countries of the EU. And these figures should rapidly increase, due to the ageing of the European population. To respond to this major concern for citizens, Ministers wish to co-ordinate national efforts to create a genuine “Alliance against cancer”, while respecting national conditions and priorities.

1. For many years, the European Union has already developed and funded initiatives with regard to epidemiological surveillance, screening, prevention, exchange of good practices and research against cancer. But such initiatives do not make it possible for all Europeans to profit from the best cancer programmes recently devised by many Member States. It is necessary to promote joint actions in order to further increase the effectiveness of national measures and improve equal access to prevention and treatment for all citizens.
2. Patient management conditions must continue to be set at local or national levels that remain the most appropriate. However, the different practices in Europe in prevention, screening and treatment are potentially rich resources. To this end, it is proposed to set up an “Alliance against cancer”, based on a network of [] national cancer institutes in countries where they exist or of corresponding national structures. The network, for which all have appointed a contact in their Member States, should carry out a programme to pool together information and best practice in prevention, screening and medical treatment. The French cancer institute, in association with any other Member State willing to join, offers to serve as the secretariat.
3. In order to enhance our knowledge of the illness, a project should be further discussed of a network of tumour databanks in Member States that possess such facilities to exchange the ensuing results and materials with the view of creating a European tumour resource centre. This type of networking should seek the inter-operability among available bio-data information systems to manage tumour databanks using shared standards.
4. Finally, it is proposed to establish a European Consortium for a "proteomic biomarker discovery research programme". The discovery of biomarkers for propensity to cancer, early detection, prognosis or prediction in response to treatment will prompt major and far-reaching developments in the fight against cancer and constitutes genuine grounds for hope for patients. These biomarkers, essentially proteins (proteome), raise the issue of their immense quantity and complexity. On the basis of the "Human Genome Project" methods, it is proposed to pool tools, methods and results in exploring proteome for various European teams among which the work completed has been allocated so that they can all meet the challenge of quickly identifying and demonstrating the value of the most important cancer biomarkers.

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II – Combating HIV/AIDS together

The HIV/AIDS epidemic is still a major challenge in the world infecting about 40 million people and affecting many more, but also in Europe and at the frontiers of our continent. HIV/AIDS remains an incurable and lethal disease. Although there have been improvements in access to prevention, testing, treatment and care, they are unevenly spread among European citizens, and even more among the disadvantaged regions of the rest of the world.

Further to the Dublin and Vilnius ministerial Declarations, the working document of the European Commission on comprehensive approach on HIV/AIDS in the Community and its neighbouring countries is welcomed. As recognised during the 6th December 2004 Council discussions, for this combat, the EU should use its resources to develop a vaccine and to support co-ordination of efforts between Member States.

[] The search for new prevention technologies including microbicides and vaccines suffers from inadequate financing and a need for better co-ordination. Although more than one-third of all potential vaccines currently under clinical development worldwide result from European research, 90% of vaccine tests in Phase I take place in the USA.

Collaboration across the EU on all aspects of the AIDS agenda is crucial, including Europe's ongoing engagement in global initiatives and efforts such as UNAIDS and the Global Fund for AIDS, TB and Malaria.

To strengthen efforts, for the fight against HIV/AIDS, the following is proposed:

5. Continuing exchanges on HIV/AIDS in European councils in charge of health issues, and at the next European Summit to define a coherent European strategy and action plan to counter the epidemic in the EU and in the neighbouring countries. As it was recently pointed out at the Dublin and Vilnius Ministerial Conferences, HIV and AIDS have progressed at an alarming rate in the Baltic States of the European Union, and at its borders, in Eastern Europe (Russia, Ukraine and Belarus) and in central Asia, where two million people live with the virus and where the number of new infections each year is estimated at 280,000. We reiterate our will to develop, from 2005 onwards, systematic exchanges of best practices from national strategies to combat the HIV/AIDS epidemic, organised and supported by the Commission, which require the involvement of all parties involved in prevention treatment and care, including people living with HIV/AIDS.
6. Establishing a European network of clinical trials to search for a vaccine. The scientific community generally acknowledges that insufficient, disparate and lacking resources undermine the chances of emergence of a European vaccine. At the Paris meeting of Health Ministers from seven European countries developing candidate vaccines on 19 October 2004, it was decided to improve the efforts made by European research laboratories. This objective was restated at the Council of Health Ministers meeting on 6 December 2004.

Subsequently, at the request of the seven Ministers, a group of experts convened and defined a European network project for clinical research on AIDS vaccines. The members of this network agree to seek

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financing together as part of the 6th Framework Research Programme (FP6) in autumn 2005. The aim of the network is to implement a joint research strategy and establish a shared system of clinical trials of sufficient size to develop candidate vaccines. The conditions for financing the development of subsequent clinical trials must be drafted as proposals from this network. Close collaboration with initiatives developed both at European level (EDCTP¹, FP6, etc.) and worldwide (GHAVE-Global HIV & AIDS Vaccine Enterprise & GAVI - Global Alliance for Vaccine and Immunization) must be ensured. EU engagement in the development of the Global HIV & AIDS Vaccine Enterprise , particularly during the stakeholder meeting in London on May 24th & 25th 2005 and beyond will provide an opportunity for a strong global European voice in HIV vaccine development. In this context, the EU should commit to narrowing the funding gap for research and development into new prevention technologies, including both microbicides and vaccines.

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III – Strengthening the health protection against current and future threats

Were Europe to be struck in the near future by an influenza pandemic, only a global, co-ordinated response would be effective, because viruses know no frontiers. This is why we must make the construction of a European health "shield" one of the European Union's priorities.

It is vital to be prepared to cope with emergencies and crises by means of an efficient alert and response system at European level. To develop a European monitoring and alert system, the support of the ECDC, currently under development is vital. It will not, however, suffice for, as long as the response to alerts is not also better co-ordinated. The Constitutional Treaty confirms the responsibility of Member States to establish a response. This is why a co-ordinated strategy must be developed as soon as possible and before the end of 2005 in line with the June 2004 Council's conclusions concerning the co-ordination of physical measures to isolate goods and persons in the event of a crisis, the constitution of anti-viral and treatment stockpiles and the development of new vaccines against subsequent threats.

7. Member States and the Commission, in conjunction with WHO, should reinforce the development and the implementation of a shared strategy. This strategy may need to combine public and private expertise and resources of both the pharmaceutical industry and public research institutions concerned. Such a strategy addressing the risks of an influenza pandemic should make it possible to develop similar strategies addressing other transmissible illnesses.
8. Strengthening the European health warning system: the new ECDC is [] cornerstone of such a strategy. To enable Member States that will have to respond to be fully involved in the development of the warning and response system, the head of the Centre will have to make regular presentations to the Council assessing the epidemiological situation both for influenza pandemics and for other transmitted diseases. Presentations will enable Health Ministers to co-ordinate the responses they decide to implement. In order to achieve such an objective, it is essential that the Centre becomes fully operational in short time period.
9. Articulating and co-ordinating national decisions to respond to crises in terms of isolation and mobility control measures for goods and persons. To ensure effective co-ordination of emergency measures, the European Commission, with the support of the ECDC, should reinforce early warning and response system for the prevention and control of communicable diseases, linking all the administrations concerned by these measures. Crisis simulation exercises, to ensure the effectiveness of the network and evaluate the interoperability of national plans, should regularly be organised, such as those foreseen by the Commission for Autumn 2005.

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10. Accelerating the development of an influenza pandemic vaccine: vaccines against influenza pandemics can be produced only once the pandemic has been declared and the viral strain has been identified. Thus, new incentives are required to stimulate the development of such vaccines and ensure manufacture from the onset of the epidemic. Precious time can be saved if all the tools to develop and manufacture the vaccine are in place. Unfortunately, these tools are currently not sufficiently developed. To plan ahead against such a threat, there must be encouragement to develop new vaccines, including by co-ordinated public incentives at European level. This action is the responsibility of the Member States that must lean upon an organisation at European level enjoying sufficient means and resources.

There is a need for a European initiative to accelerate the development and manufacture of future pandemic vaccines, as already initiated by the Commission.

This initiative may need to be organised on the basis of a public-private sector partnership including the European vaccine manufacturers and the public research institutes concerned. It is intended to provide scientific and strategic steering to develop pandemic vaccine prototypes quickly and ensure data to assess the effectiveness and safety of these vaccines. It may also need to explore the development of new production tools tailored to fast, massive production that can be mobilised in the event of a crisis.

11. Given new transmissible agents, a European exchange network between expert committees in charge of vaccine recommendations in Member States could be established under the aegis of the ECDC. The Centre could use the work of this network for issuing proposals for a joint vaccine development strategy or new treatment measures against new pandemics. The Centre could rely on this work to elaborate scientific guidelines on vaccination strategies and development of vaccines to combat new epidemics.

Finally, the search for a more effective European response does not cover all the challenges raised by contemporary health threats. This response can't be developed independently of the international situation. This is why the Health Ministers reiterate their expectations from the WHO and from the conclusion of current negotiation rounds concerning the new International Health Regulation (IHR). The revamped instrument to identify and respond to international health threats is the cornerstone of international health safety. This is why the adoption of the IHR at the next WHO health assembly in May is highly desirable.

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¹ EDCTP : European & Developing Countries Clinical Trials Partnership