

10090/02 (Presse 182)

2440th Council meeting

- HEALTH -

Luxembourg, 26 June 2002

President : **Ms Celia VILLALOBOS TALERO**

Minister for Health and Consumer Affairs of the
Kingdom of Spain

Internet: <http://ue.eu.int/Newsroom>
E-mail: press.office@consilium.eu.int

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PARTICIPANTS

The Governments of the Member States and the European Commission were represented as follows:

Belgium:

Ms Magda AELVOET

Minister for Consumer Protection, Public Health and the Environment

Ms Nicole MARECHAL

Minister for Youth Welfare and Health (French Community)

Denmark:

Mr Lars Løkke RASMUSSEN

Minister for the Interior and Health

Mr Ib VALSBORG

State Secretary, Ministry of Health

Germany:

Ms Ulla SCHMIDT

Federal Minister for Health

Greece:

Mr Ektor NASIOKAS

Minister for Health and Social Welfare

Spain:

Ms Celia VILLALOBOS TALERO

Minister for Health and Consumer Affairs

France:

Mr Jean-François MATTEI

Minister for Health, the Family and Disabled Persons

Ireland:

Mr Micheál MARTIN

Minister for Health and Children

Italy:

Mr Girolamo SIRCHIA

Minister for Health

Luxembourg:

Mr Carlo WAGNER

Minister for Health and Social Security

Netherlands:

Ms Els BORST-EILERS

Deputy Prime Minister and Minister for Health, Welfare and Sport

Austria:

Mr Reinhart WANECK

State Secretary, Federal Ministry of Social Security and Generations

Portugal:

Mr Luis Filipe PEREIRA

Minister for Health

Finland:

Ms Eva BIAUDET

Minister for Health and Social Services

Mr Lars ENGQVIST

Minister for Health and Social Affairs

Sweden:

Mr Lars ENGQVIST

Minister for Health and Social Affairs

United Kingdom:

Mr John HUTTON

Minister of State for Health

* * *

Commission:

Mr Erkki LIKANEN

Member

Mr David BYRNE

Member

TOBACCO CONTROL**– WHO FRAMEWORK CONVENTION**

The Council was briefed by the Commission on the progress of the negotiations concerning the Framework Convention on Tobacco Control (FCTC) of the World Health Organisation (WHO) and on the priority areas that had been identified during the negotiations. The fifth session will take place from 14 to 25 October 2002.

Several delegations stressed the need for the Community and the Member States to establish a common position on this subject in order to promote an ambitious health policy.

In general, the delegations and the Commission took the view that the following topics should be examined in more detail:

- advertising of tobacco products
- passive smoking
- tax-free sales of tobacco products

The Council noted the comments by the Member States and the Commission and asked them to continue their discussions so that a substantial contribution could be made to the next negotiating session.

– ***ADVERTISING AND SPONSORSHIP OF TOBACCO PRODUCTS***

The Council was briefed by the Presidency on the progress of discussions concerning the proposal for a Directive of the European Parliament and of the Council on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products.

The proposal was sent by the Commission to the Council in June 2001. It seeks to harmonise the Member States' existing rules on the advertising of tobacco products via the print media, radio and the Internet as well as the sponsorship by tobacco-producing undertakings of events and activities, insofar as this entails distortions of cross-border trade. It also seeks to supplement a Community Directive of 1989 prohibiting the television advertising and the sponsorship of tobacco products.

The Directive is intended to replace an earlier Directive on the same subject, which was annulled by the Court of Justice on 5 October 2000 because some of its provisions were deemed not to be in conformity with the legal basis on which it was adopted. The proposed Directive is subject to the codecision procedure with the European Parliament and is based on Articles 47, 55 and 95 of the Treaty (qualified majority of the Council).

The Presidency emphasised the importance which the Council attaches to the early adoption of the European Parliament's Opinion on this dossier. The European Parliament should deliver its Opinion in the autumn of 2002, a public debate having already been held in that forum in April, attended by, among others, Commission representatives, national experts and professionals working in the field. The dossier will have to be passed on to the incoming Presidency, which will examine it once the European Parliament's Opinion has been delivered.

– ***PREVENTION OF SMOKING***

The Council noted the Commission's presentation of a proposal for a Council Recommendation on the prevention of smoking and on initiatives to improve tobacco control (10237/02), which mainly focuses on young people and seeks to supplement existing Community provisions on the subject (the Tobacco Products Directive of June 2001 and the proposal for a Directive on the advertising of tobacco products).

The Commission suggests measures to reduce the supply of tobacco products to children and adolescents, and in particular to:

- restrict their access to tobacco vending machines and to distance and Internet sales;
- remove tobacco products from self-service displays;
- prevent the lower-priced sale of packets of fewer than 20 cigarettes;
- requiring vendors to establish that purchasers have reached the minimum age specified in national law.

It also calls on the Member States to ensure that certain forms of advertising and promotion are not targeted at children and adolescents (use of tobacco brand names on goods, clothing or services other than tobacco products; distribution of promotional items; use of outdoor billboards and posters; advertising in cinemas) and to require tobacco manufacturers to declare the expenditure they devote to advertising, marketing, sponsorship and promotion campaigns, to provide suitable protection against passive smoking in workplaces, enclosed public places and public transport, and to strengthen the smoking prevention programmes.

The proposed recommendation takes account of the negotiations currently going on in connection with the WHO Framework Convention on Tobacco Control.

The Council agreed to examine the proposal with a view to adopting it at an early date.

PREVENTION AND REDUCTION OF RISKS ASSOCIATED WITH DRUG DEPENDENCE

The Council took note of the presentation by the Commission of a proposal for a Recommendation on the prevention and reduction of risks associated with drug dependence.

The proposal for a Recommendation specifically addresses the second public health target defined by the European Union Strategy on Drugs (2000-2004), that is to say, to reduce substantially over five years the incidence of drug-related health damage and the number of drug-related deaths using risk reduction measures which have been shown to be successful in achieving that aim.

It encourages Member States to combat the spread of drug-related infections in particular by:

- providing information to drug users and their families to limit the spread of risk;
- carrying out outreach work in urban and rural areas to overcome the difficulty of reaching a drug-user population which is frequently outside the normal channels of health care;
- establishing a health care system with medical, social and psychological components and promoting systematic vaccination against hepatitis B;
- making available substitution products (taking steps to ensure that they are not diverted) and anti-infection devices (condoms, needle exchange points).

Commissioner BYRNE recalled that drugs were directly responsible for 7000 deaths a year in the Community, as well as being an indirect cause of death (as a result of acts of crime, traffic accidents, suicides, and AIDS).

The Council agreed to examine the proposal as soon as possible with a view to adopting it in the near future.

HUMAN TISSUES AND CELLS

The Council took note of the presentation by the Commission of a proposal for a Directive setting standards of quality and safety for the donation, procurement, testing, processing, storage and distribution of human tissues and cells in order to ensure a high level of health protection in the European Community (10238/02).

The Directive should make it possible in particular to:

- create a register of bodies operating in the sector within the Community;
- set minimum quality and safety standards and define the necessary professional qualifications and training requirements;
- organise controls and apply sanctions in the Member States;
- lay down minimum rules and mandatory procedures for all instances of use of these human products (donation, procurement, experimentation, processing, storage and distribution).

The Directive does not apply to the use of human blood organs and blood products.

The Council agreed to study the proposal with a view to adopting it in the near future.

PATIENT MOBILITY – Council Conclusions

- "1. The Council and the representatives of the Member States meeting in the Council recognise that the health care systems in the European Union share common principles of solidarity, equity and universality, despite their diversity. They also recognise the emerging interaction between health systems within the European Union particularly as a result of the free movement of citizens, and their desire to have access to high quality health services.
2. The Council recalls that according to Article 152 of the Treaty, Community action in the field of public health must fully respect the responsibilities of the Member States for the organisation and delivery of health services and medical care. However, it recognises that other developments, such as those relating to the single market, have an impact on health systems. The Council is concerned that these should be consistent with the Member States' health policy objectives, and the common principles outlined above. It therefore considers that there is added value in examining certain health issues from a perspective that goes beyond national borders. In this context it welcomes the debate at the seminar of health ministers held in Malaga in February 2002 which set out a number of priority issues for further cooperation and takes note of the expert discussions on this subject.
3. The Council takes note of the ongoing work on the future of healthcare and care for the elderly being carried out by the Social Protection Committee and the Economic Policy Committee on the basis of the conclusions of successive European Councils. It also notes the work being undertaken on the reform and modernisation of Regulation 1408/71 which should provide a simplified framework to support, inter alia, patient mobility. It underlines the necessity to take health concerns and patients' interests fully into account in this process in which the delivery of care shall be another main concern together with the administrative issues. The relevant instances of the Community and its Member States should be fully involved regarding the implications of this process. In particular, the Ministers of Health should be fully involved in this process.
4. With regard to developing cross-border cooperation, the Council and Member States' representatives recognise that bilateral or regional arrangements, which respect the competence of Member States to organise their health care systems and which are in accordance with relevant Community legislation, can play an important role, and they underline the importance of sharing information about such initiatives. They emphasise that patient mobility, especially concerned with tourism or long-term residence abroad, presents particular challenges in terms of the need to exchange clinical and other information, in order to ensure proper follow-up and continuity of care. They recognise the importance of cooperation, inter alia, to examine the benefit of reference centres, in order to facilitate the most effective treatment for those diseases requiring specialist interventions.

5. The Council recognises that the new programme of Community action in the field of public health together with, inter alia, the new research and telematics programmes provide a framework to pursue a number of issues in relation to mobility of patients, in particular aspects relating to information and exchanges of experience.
6. In the light of these considerations, the Council and Member States' representatives consider that there is a need to strengthen cooperation in order to promote the greatest opportunities for access to health care of high quality while maintaining the financial sustainability of healthcare systems in the European Union. The imminent enlargement of the European Union makes this even more imperative.
7. To this end the Council and the representatives of the Member States meeting in the Council:
 - recognise that there would be value in the Commission pursuing in close cooperation with the Council and all the Member States – particularly health ministers and other key stakeholders – a high level process of reflection. This process should be closely coordinated with relevant work ongoing in different fora, including action already initiated in the context of the Lisbon process. This high-level process of reflection, about which they wish to be kept regularly informed, should aim at developing timely conclusions for possible further action;
 - welcome the Commission's intention to take forward work in this field, inter alia by including relevant actions in its work plan for the programme of Community action in the field of public health.
8. The Council and Member States' representatives will return to this issue at the next meeting of the Health Council, taking into account the developments of the reflection process mentioned above."

BRIEFING BY THE PRESIDENCY

The Presidency briefed the Council on the following subjects:

- promoting health at work: a Presidency note (10048/02) stresses the importance of promoting health at work and lists the elements required to implement an adequate policy for that purpose. This point is related to a briefing on safety at work by the Presidency to the Employment and Social Policy Council;
- promoting cardiovascular health: a Presidency note (9752/02) underlines the importance and effectiveness of a policy of this kind, which could be addressed within the framework of the Health Action Programme, in particular by improving the amount of information;
- epidemiological surveillance and research in European health systems: two notes from the Presidency (9937/02 and 9892/02) describe the outcome of the Madrid and Granada conferences on these subjects, at the end of which it was concluded that greater resources needed to be allocated to Member States' information networks, that any political commitment should include all the parties involved in the process, and that a framework for research should be established within the various European health systems;
- future activities of the Council (Employment, Social Policy, Health and Consumer Affairs): the Council noted that future Presidencies would set provisional agendas and dates for meetings in the light of, in particular, the conclusions of the Seville European Council.

BIOTERRORISM

Over lunch Ministers held an exchange of views on bioterrorism (10082/02).

REVIEW OF PHARMACEUTICAL LEGISLATION

The Council held a policy debate on the basis of a Presidency questionnaire (10058/02) on three proposals – a Regulation and two Directives – the main aims of which are to achieve completion of the single market in the medicinal products sector, to improve the competitiveness of the pharmaceutical industry (particularly small and medium-sized enterprises) and to simplify Community legislation.

The Opinion of the European Parliament at first reading should be available in October 2002.

Two topics were discussed at this stage following the proceedings of the Working Party:

- the scope of the proposal for a Regulation: the text provides for extension of the compulsory centralised Community procedure to medicinal products for human or veterinary use containing new active substances; a majority of delegations wanted to be able to continue to choose between a centralised system and a system of national authorisations with the principle of mutual recognition. Some delegations, however, made distinctions depending on whether the medicinal product was for human or veterinary use. Some delegations said they could support an extension of the scope for medicinal products for human use only. Delegations which recommended an optional system put forward the following main arguments:
 - ▶ several delegations wanted the Commission to provide a better definition of medicinal products containing new active substances;
 - ▶ several delegations expressed concern regarding the situation of small and medium-sized enterprises and argued that some flexibility was the best solution for them;
 - ▶ some delegations expressed fears that extension of a centralised procedure would not take sufficient account of the views of national authorities;
 - ▶ as regards medicinal products for veterinary use, some delegations pointed out that, since in some cases their use and authorisation involved only a few regional animal species (e.g. northern Finland), a national authorisation system would be preferable.

Some delegations stressed in particular the need to improve the technical resources of the European Agency for the Evaluation of Medicinal Products (EMEA) – computerised files, national databases – and to extend its evaluation methods, along the lines of the methods available to the United States Food and Drug Administration.

- the new composition of the Management Board of the European Agency for the Evaluation of Medicinal Products (EMA): under the proposal this Board would consist of four representatives of the Member States, four representatives of the European Parliament, four representatives of the Commission and four representatives of patients and the industry; a very large majority of delegations wanted to maintain representation by Member States only. Two delegations stressed in particular the need for the Management Board to have a composition different from that of the European Food Safety Authority (EFSA) – a consultative body – taking account of the executive role of the EMA in issuing authorisations for placing medicinal products on the market.

The Council agreed to take account of these positions expressed by the Member States when continuing its discussions in the second half of 2002.

HERBAL MEDICINAL PRODUCTS

The Council took note of the presentation by the Commission of a proposal for a Directive (6240/02) concerning traditional herbal medicinal products. This text amends a recent Directive establishing a Community code on medicinal products for human use and lays down specific simplified registration arrangements for these products under certain conditions to facilitate their marketing. It is intended to complete the achievement of the single market by allowing free movement of these products while guaranteeing their safety and to allow European small and medium-sized enterprises in the sector to increase their profits.

The Council agreed to examine this proposal in the second half of 2002.

ROLE OF MEDICAL DEVICES – Council conclusions

"THE COUNCIL OF THE EUROPEAN UNION,

welcoming the continuous work carried out by the Commission and the Member States on the coherent implementation of the medical devices directives,

stressing the importance of medical devices in health care and social care, in improving the level of health protection, the quality of life of citizens, and the full participation in society of persons with disabilities,

ADOPTS THE FOLLOWING CONCLUSIONS:

The Council,

1. *ACKNOWLEDGES* that medical devices present particular features in relation to other sectors of health care and that the Community regulatory framework put into place for medical devices has to ensure both a high level of health protection and timely market access for the benefit of patients;
2. *ACKNOWLEDGES* the importance of in-vitro diagnostic medical devices from the point of view of health policy, due to their role in diagnosing and monitoring different medical conditions and, in particular, in the detection of transmissible diseases;
3. *ACKNOWLEDGES* the impact that emerging new technologies, in particular human tissue and cell engineered products, may have in many areas of healthcare and the need to define an appropriate legal framework for those matters, which ensures a high level of health protection;
4. *HIGHLIGHTS* the importance for the implementation of Community directives on medical devices of administrative cooperation between Member States as well as between Member States and the Commission in order to achieve a common understanding, in particular with respect to the designation and monitoring of notified bodies, market surveillance, evaluation of clinical data and adverse events management, and recognises the need to extend this cooperation to candidate countries, where appropriate;
5. *WELCOMES* the current review of the medical devices directives and the actions already being undertaken to ensure a more coherent application of some elements of the directives, in particular the conformity assessment procedures and the clinical evaluation of high risk devices;

6. *WELCOMES* the Commission's Communication on Community and national measures in relation to breast implants of 15 November 2001 ¹, to be introduced to improve safety and quality control as well as post market tracking and surveillance, to ensure appropriate information for patients and to foster research and further development of breast implants; and considers that this approach should be extended to other devices, wherever appropriate;
7. *HIGHLIGHTS* the international dimension of the medical devices sector and acknowledges the need to aim for a high level of health protection through cooperation and exchange of views with third countries and international health organisations, and acknowledges the importance of the work performed by the Global Harmonisation Task Force in developing common guidance for the sector and its role in assisting other countries;
8. *ENCOURAGES* Member States - whilst acknowledging the responsibility of the manufacturer for providing the user, including lay-persons, with adequate instructions for use – to further develop the measures necessary to ensure appropriate and correct use of medical devices, taking into account, in particular,
- the need for proper training in the use of devices and for the necessary maintenance of equipment, given the increasing complexity of devices,
 - the need to ensure availability and awareness of proper documentation and reports on critical medical procedures and acts,
 - the need to ensure, where appropriate, that efficient patient traceability and follow-up procedures are in place, to enable necessary measures to be taken promptly;
9. *INVITES* the Commission
- to present the conclusions to be drawn from the current review process of the medical devices directives and to propose, where necessary, appropriate measures to be taken;
 - to continue to ensure, together with Member States, a coherent implementation of the medical devices directives."

¹ COM(2001) 666 final.

MEDICAL DEVICES

The Council took note of information from the Commission providing details of the evaluation and revision of the application of Directive 93/42/EEC concerning medical devices. The Council (Health) on 15 November 2001 had previously received this information in response to a request from Belgium. A working paper should be available by the end of the year.

MISCELLANEOUS**– *VIOLENCE AGAINST WOMEN***

The Presidency gave the Council details of a study on violence against women in the Member States of the European Union, together with a Guide on Best Practice for the eradication of this phenomenon (9184/02).

– *THE FIGHT AGAINST AIDS*

The Presidency briefed the Council on this subject on the basis of a note (9944/02). This was a project for a "hospital solidarity network against AIDS" supported by Spain, France, Italy, Luxembourg and Portugal, involving collaboration between the hospitals of these Member States and hospitals in Africa and Latin America.

– *HIGH LEVEL WORKING PARTY REPORT ON INNOVATION AND SUPPLY OF MEDICINAL PRODUCTS*

The Council took note of information from Commissioners LIIKANEN and BYRNE concerning the conclusions of the report from the High Level Working Party submitted to the President of the European Commission on 7 May 2002. This group, known as the "G10", was set up to examine the European pharmaceutical industry's competitiveness while at the same time guaranteeing a high level of health protection. The report contains fourteen recommendations, several of which fall within the Member States' sphere of competence.

ITEMS APPROVED WITHOUT DEBATE

The documents whose references are given are available on the Council's Internet site <http://ue.eu.int>. Acts adopted with statements for the Council minutes which may be released to the public are indicated by an asterisk; these statements may be obtained by following the procedure indicated above or from the Press Office.

HEALTH

Programme of action in the field of public health *

The Council adopted the Decision establishing a programme of Community action in the field of public health for the period 2003-2008 (3627/92 + 9532/02 ADD 1), in accordance with the agreement concluded in conciliation with the European Parliament on 8 May 2002. The programme, which will replace eight Community action programmes currently running, will have a budget of EUR 312 million over the six years.

This programme complements the public health policy pursued by the Member States and is intended to guarantee a high level of protection in the defining and implementing of Community policies by promoting an integrated and intersectoral health strategy.

More particularly, its purpose is to:

- improve information and knowledge relating to public health;
- enhance the ability of public authorities and health systems to respond rapidly and in a coordinated manner to health threats;
- promote health and the prevention of disease by addressing key health issues in all policies and activities.

CUSTOMS UNION

Common Customs Tariff for certain industrial, agricultural and fisheries products

The Council adopted a Regulation temporarily suspending the autonomous common customs tariff duties on certain industrial, agricultural and fishery products (8716/02). This Regulation amends the list in Regulation No 1255/96 of products subject to total or partial suspension of customs tariffs on importation into the Community.

Tariff quotas for certain agricultural and industrial products

The Council adopted a Regulation on autonomous Community tariff quotas for certain agricultural and industrial products (8694/02). The Regulation amends the list in Regulation No 2505/96 laying down reduced or zero rate import quotas for these products, by opening new quotas and increasing or extending existing quotas to meet Community demand under more favourable conditions.

CONSUMERS**Distance marketing of financial services ***

The Council adopted, with the Luxembourg delegation abstaining, the Directive concerning the distance marketing of consumer financial services, incorporating all the amendments voted by the European Parliament at second reading (3633/02 + 10283/02 ADD 1).

This Directive amends Directives 90/619/EEC, 97/7/EC and 98/27/EC and is designed to set a legal framework promoting the operation of the internal market while ensuring a high level of consumer protection. In doing so it complements the existing sectoral provisions on financial services and fills a vacuum left by the general Directive on the distance marketing of consumer goods.

