COUNCIL OF THE EUROPEAN COMMUNITIES
GENERAL SECRETARIAT

# PRESS RELEASE

**7450/91 (Presse 131)**

**1509th Council meeting**
**- INTERNAL MARKET -**
**Brussels, 22 July 1991**

**President : Mr Piet DANKERT**
**State Secretary**
**for Foreign Affairs**
**of the Kingdom of**
**the Netherlands**

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

Belgium

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| Mr Paul de KEERSMAEKER | State Secretary for European Affairs |

Denmark

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| Mr Christopher Bo BRAMSEN | Head of Department, Ministry of Industry |

Germany

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| Mr Dieter von WÜRZEN | State Secretary, Federal Ministry of Economic Affairs |

Greece

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| Mr Sotirios HATZIGAKIS | Deputy Minister for Trade |

Spain

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| Mr Carlos WESTENDORP | State Secretary for Relations with the European Communities |

France

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| Mrs Elisabeth GUIGOU | Minister for European Affairs |

Ireland

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| Mr Terry LEYDON | Minister of State at the Department of Industry and Commerce with special responsibility for Trade and Marketing |

Italy

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| Mr Pierluigi ROMITA | Minister for Community Policies |

Luxembourg

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| Mr Georges WOHLFART | State Secretary for Foreign Affairs and Foreign Trade |

Netherlands

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| Mr Piet DANKERT | State Secretary for Foreign Affairs |

Portugal

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| Mr Vitor MARTINS | State Secretary for European Integration |

United Kingdom

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| Mr Edward LEIGH | Parliamentary Under-Secretary of State, Department of Trade and Industry |

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Commission

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| Mr Martin BANGEMANN | Vice-President |
| Mr Filippo Maria PANDOLFI | Vice-President |

MEDICINAL PRODUCTS

Rational use of medicinal products for human use

The Council reached a political agreement with a view to the establishment of a common position on three proposals for Directives on the rational use of medicinal products for human use, regarding:

- labelling and package leaflets;
- legal status for supply;
- wholesale distribution.

The Common positions will be formally adopted in the near future, after finalization of the texts.

The aim of these Directives is to facilitate the free movement of medicinal products, whilst guaranteeing a high level of consumer protection.

The texts as they emerged from the agreement may be summarized as follows:

- Labelling and package leaflets

  The purpose of this Directive is to harmonize the information supplied to the user of a medicinal product which will have to appear on the outer packaging of the product concerned and in the package leaflet which it will in future be compulsory to include in the packaging.

  It supplements and gives details with respect to the application of Directives 65/65 and 75/319 on the approximation of the provisions laid down by law, regulation or administrative action relating to medicinal products and proprietary medicinal products, as last amended by Directive 89/341.

The Member States will have to comply with the Directive by 1 January 1993. However, until 1 January 1994, they will not refuse an application for authorization to place a medicinal product on the market or for the renewal of an existing authorization, where the labelling and the package leaflet do not comply with the Directive.

As regards the labelling, the outer packaging or immediate packaging of any medicinal product must bear, in a clear and easily comprehensible form, a set of particulars concerning, inter alia, the name of the product, its ingredients and pharmaceutical form, a list of the excipients known to have a recognized action or effect, the method and route of administration, special warnings and special precautions for storage and disposal of unused products and the expiry date.

Member States may require the use of certain forms of labelling making it possible to indicate the price of the medicinal product, the reimbursement conditions of social security organizations, the legal status for supply to the patient, and identification and authenticity.

The package leaflet will have to include, in clear and understandable terms:

- the name of the medicinal product, a full statement of its ingredients expressed qualitatively and a statement of the active ingredients expressed quantitatively (using their common names), the pharmaceutical form and the contents by weight, by volume or by number of doses, the pharmaco-therapeutic group or type of activity (in terms easily comprehensible for the patient), the name and address of the holder of the authorization for placing the medicinal product on the market and of the manufacturer;

- the therapeutic indications;

- a list of information which is necessary before taking the medicinal product: contra-indications, appropriate precautions for use, forms of interaction with other medicinal products and other forms of interaction (alcohol, tobacco, foodstuffs) which may affect the action of the medicinal product, special warnings;

- the necessary and usual instructions for proper use of the medicinal product;

- a description of the undesirable effects which can occur under normal use of the medicinal product and, if necessary, the action to be taken in such a case;

- a reference to the expiry date indicated on the label and the date on which the package leaflet was last revised.

The competent authorities will be able to decide that certain therapeutic indications are not to be mentioned in the package leaflet, where the dissemination of such information might have serious disadvantages for the patient.

As necessary, the Commission, assisted by a Committee made up of representatives of the Member States, will publish guidelines concerning in particular the formulation of certain special warnings for certain categories of medicinal products, the particular information needs relating to self-medication, the legibility of the particulars on the labelling and package leaflet, methods for identification and authentication, and the list of excipients which must feature on the labelling.

- Legal status for the supply of medicinal products

The aim of this Directive, which is scheduled to enter into force by 1 January 1993, is to harmonize the conditions for supplying medicinal products to patients by establishing a legal classification system for medicinal products, in particular for those that can be obtained only with a doctor's prescription.

One of the consequences of this harmonization will be to allow persons to move around within the Community with reasonable quantities of medicinal products lawfully obtained for their personal use or to have similar quantities sent to them from one Member State to another.

Medicinal products will be subject to renewable or non-renewable medical prescription where they:

- are likely to present a danger either directly or indirectly, even when used correctly, if utilized without medical supervision, or

- are frequently and to a very wide extent used incorrectly, and as a result are likely to present a direct or indirect danger to human health, or

- contain substances or preparations thereof the activity and/or side effects of which require further investigation, or

- are normally prescribed by a doctor to be administered parenterally.

Member States may also provide for two sub-categories of medicinal products:

- those subject to special medical prescription, in particular where they contain substances classified as narcotic or psychotropic substances;

- those subject to restricted prescription (intended for use in a hospital environment or by specialists).

The competent authorities of each Member State will have to specify the legal status for the supply of the medicinal product when a marketing authorization is granted.

In addition, they will draw up a list of the medicinal products subject on their territory to medical prescription, specifying, if necessary, the category of classification.

- Wholesale distribution of medicinal products

The aim of this Directive, with which Member States will have to comply by 1 January 1993, is to exercise control over the wholesale distribution of medicinal products, in order, inter alia, to facilitate the withdrawal of defective products, from the market and allow more effective efforts against counterfeit products.

The wholesale distribution of medicinal products in the Community will in future be subject to the acquisition of a special authorization granted by the competent authority of each Member State and recognized by the other Member States.

In order to obtain the authorization, the applicant will have to fulfil certain essential requirements and it will be the responsibility of the Member State concerned to ensure that they are met.

Those requirements state that applicants must have qualified personnel and a person designated as responsible, and suitable and adequate premises, installations and equipment such as to ensure proper conservation and distribution of the medicinal products.

In addition, holders of an authorization for the wholesale distribution of medicinal products will have to comply with a number of obligations; in particular they will have to have an emergency plan which will ensure effective implementation of any recall from the market.

Wholesalers will also have to keep records for a period of five years, giving, for any transaction in medicinal products received or dispatched, information on the date, name of the medicinal product, quantity received or supplied, and name and address of the supplier or consignee.

The Commission, in consultation with the Committee for Proprietary Medicinal Products and the Pharmaceutical Committee, will publish guidelines on good distribution practice, with which holders of authorizations for the wholesale distribution of medicinal products will have to comply.

Advertising of medicinal products

The Council reached a political agreement with a view to the establishment of a common position on a Directive on advertising of medicinal products.

The common position will be formally adopted in the near future, after finalization of the texts.

This Directive, which forms part of the completion of the internal market in medicinal products for human use, is designed in particular to harmonize the conditions under which pharmaceutical advertising is permitted and to lay down the requirements to be met by such advertising.

In this connection, separate arrangements have been laid down, to apply as from 1 January 1993, for advertising to health professionals and to the general public.

The agreement prohibits any advertising to the public of medicinal product in respect of which a marketing authorization has not been granted.

In general, the advertising of a medicinal product must not be misleading and will have to encourage the rational use of it, by presenting it objectively and without exaggerating its properties.

All parts of the advertising of a medicinal product will also have to comply with the particulars listed in the summary of product characteristics.

The arrangements concerning monitoring of this type of advertising provided for in the text are similar to those laid down in Directive 84/450 on misleading advertising. Two alternative monitoring mechanisms are allowed: prior statutory vetting or voluntary monitoring by the relevant professional bodies.

Advertising to the general public of medicinal product which are available on medical prescription only is prohibited [1].

Advertising of other medicinal products will have to be set out in such a way that it is clear that the message is an advertisement, and that the product is clearly identified as a medicinal product.

It will also have to include the information necessary for correct use of the medicinal product and an express, legible invitation to read carefully the instructions on the package leaflet or on the outer packaging, according to the case.

(1) This prohibition is already laid down as regards television broadcasting activities by Directive 89/552 ("Television without frontiers").

The Directive sets out an exhaustive list of prohibitions regarding the content of advertisements with the aim of preventing misunderstandings which may harm consumers' health.

It does not prevent Member States from authorizing reminder advertising including only the name of the medicinal product, if they wish to.

Advertising to health professionals and any documentation relating to medicinal product which is transmitted to them will have to include particulars compatible with the summary of product characteristics, and also the supply classification of medicinal product.

Medical sales representatives will have to be given adequate training by the firm which employs them and have sufficient scientific knowledge to be able to provide precise information, which should be as complete as possible about the medicinal products which they promote.

Where medicinal products are being promoted to persons qualified to prescribe or supply them, it will be prohibited to supply, offer or promise any gifts, pecuniary advantages or benefits in kind to such persons unless they are inexpensive and relevant to the practice of medicine or pharmacy.

Hospitality at sales promotion must always be reasonable in level and secondary to the main purpose of the meeting and must not be extended to other than health professionals.

It will be permitted to provide free samples on an exceptional basis only to persons qualified to prescribe them and only in limited numbers. Member States will be permitted to place further restrictions on the distribution of samples of medicinal products.

SWEETENERS

The Council reached a political agreement on a Directive on sweeteners for use in foodstuffs with a view to the adoption of a common position.

This is the first part of the comprehensive Directive provided for by the Directive on additives (89/107/EEC).

The principal aim of the proposal is to allow the free movement of foodstuffs containing sweeteners and, in this connection, to draw up a list of authorized sweeteners and the conditions under which they may be used in foodstuffs. In particular, the following sweeteners could be placed on the market with a view to their sale to the ultimate consumer or their use in the manufacture or foodstuffs:

- Sorbitol (E 420)
- Mannitol (E 421)
- Isomalt (E 953)
- Maltitol (E 965)
- Lactitol (E 966)
- Xylitol (E 967)
- Acesulfame K (E 950)
- Aspartame (E 951)
- Cyclamic acid and its Na and Ca salts (E 952)
- Saccharin and its Na, K and Ca salts (E 954)
- Thaumatin (E 957)
- Neohesperidine DC (E 959).

The proposal for a Directive also establishes maximum levels for the use of sweeteners in foodstuffs in order to protect consumers' health. Except where specially provided for, sweeteners may not be used in foods for infants or young children, as specified in Directive 89/398/EEC.

As regards the authorization of cyclamates, the Council instructed the Permanent Representatives Committee to carry out a more detailed analysis of the maximum doses authorized by the proposal for a Directive. In addition, the Scientific Committee for Food will have to provide the Commission with a further study on the metabolization of cyclamates and their possible toxicity, before the Directive is implemented. If, following examination of the results of that study, it seems necessary to change the status of cyclamates, the Commission will immediately take the appropriate measures in order to do so.

As regards the possible prohibition of sweetening of traditionally unsweetened beers on German territory, the Commission stated that the Member States could, in the case of traditional beers and manufacturing processes, retain the option of prohibiting the sweetening provided for by the Directive, where their legislation prohibits sweetening. This derogation will have no effect on the freedom of establishment of breweries or on the free movement of beer in the twelve Member States. It will also be possible to adopt the same principle in the rest of the legislation necessary for the completion of the internal market in foodstuffs, with the same aim of safeguarding traditional products and manufacturing processes.

At the end of the discussions, the Permanent Representatives Committee was instructed to finalize the text of the Directive and of the relevant statements with a view to formal adoption of the common position in the near future.

TEDIS PROGRAMME

The Council adopted a decision establishing the second phase of the TEDIS (Trade Electronic Data Interchange System) programme, scheduled to last three years from 1 July 1991.

The amount estimated as necessary for the implementation of the programme is ECU 25 million, including ECU 4 million for 1991 and ECU 6 million for 1992.

The second phase continues the work begun during the first phase (1988-1990), whilst at the same time broadening the scope of the activities, in particular in the direction of measures concerning standardization of electronic data interchange (EDI) messages, EDI needs as regards telecommunications, and sectoral and intersectoral projects bringing together the private sector and, where appropriate, certain administrations.

The objectives of the TEDIS programme are to ensure that electronic date interchange systems are established to the best effect, in view of the socio-economic importance of such systems, and to mobilize the necessary resources to achieve this end at Community level.

In order to achieve these objectives, measures will be taken and continued in the following areas:

- standardization of EDI messages;
- specific EDI needs as regards telecommunications;
- legal aspects of EDI;
- security of messages;
- multi-sector and Europe-wide projects;
- analysis of the impact of EDI on company management;
- information campaigns.

The implementation of the programme will be co-ordinated with existing or planned Community policies and activities concerning telecommunications, particularly in respect, where necessary, of initiatives under the Open Network Provision Framework Directive, the information market (IMPACT Programme), security of information systems and standardization, and in particular with the CADDIA programme and the CD project, so as to ensure the necessary interaction with the specific requirements of the exchange of electronic date.

IMPACT 2

The Council held a detailed dicusssion on the proposal for a Decision concerning the IMPACT 2 (Information Market Policy Actions) programme, the purpose of which is to set up an internal information services market.

The Council instructed the Permanent Representatives Committee to continue the discussions.

Agreement has already been reached on the duration and amount of the programme: ECU 64 million for four years.

OTHER DECISIONS CONCERNING THE INTERNAL MARKET

Insurance Committee

The Council adopted a common position on a Directive setting up an Insurance Committee, composed of representatives of the Member States and chaired by a representative of the Commission.

The Committee, which will operate in accordance with the committee procedure III(b), will assist the Commission in exercising the implementing powers conferred on it by the Council in the area of direct non-life insurance and life assurance. The Committee will also have the task of advising the Commission on the preparation of new proposals to be submitted to the Council in the same area.

The Committee will assume its functions on 1 January 1992.

Baggage controls for intra-Community flights and sea crossings

The Council formally adopted its common position on a Regulation concerning the elimination of controls and formalities applicable to the cabin and checked baggage of passengers taking an intra-Community flight and the baggage of passengers making an intra-Community sea crossing (see Press Release 7018/91 - Internal Market 18.VI.91).

MISCELLANEOUS DECISIONS

Medium-term financial assistance for Romania

Following the agreement reached at the ECOFIN Council meeting on 8 July 1991, the Council adopted a Decision providing medium-term financial assistance for Romania of a maximum amount of ECU 375 million, with a view to supporting Romania's balance of payments and strengthening its reserves. (See Press Release 7148/91, ECOFIN 8 July 1991).

Financial aid for Israel and the Palestinian population of the Occupied Territories

Following the agreement reached at the General Affairs Council meeting on 4 and 5 March 1991, and having received the Opinion of the European Parliament, the Council formally adopted a Decision on financial aid for Israel and the Palestinian population of the Occupied Territories, to reduce the consequences of the Gulf crisis, involving the following:

- for Israel, a loan of ECU 160 million raised on the market, accompanied by interest rate subsidies for which a sum of ECU 27,5 million will be earmarked in the 1991 budget, intended in particular to cover expenditure on imports;

- for the Palestinian population of the Occupied Territories, ECU 60 million in the form of grants, to be committed under the 1991 budget for financing, inter alia, social housing and hospital facilities.

Action programme for the vocational training of young people and their preparation for adult and working life (PETRA)

The Council formally adopted a Decision launching the second stage of an action programme for the vocational training of young people and their preparation for adult and working life (PETRA).

The amount deemed necessary for carrying out this programme, which will last for three years from 1 January 1992, is ECU 177,4 million, including ECU 29 million for 1991/1992 (see Social Affairs Council Press Release of 25 June 1991 - 7142/91 Presse 119).

Commercial policy

The Council adopted a Decision authorizing extension of tacit renewal of certain trade agreements concluded between Member States and third countries.

Anti-dumping

As the Council raised no objections to the draft Commission Decision accepting a price undertaking offered under the anti-dumping procedure for imports into Italy of certain asbestos cement pipes originating in Turkey and closing the investigation, the decision was adopted definitively.

Relations with Argentina

The Council adopted the Decision on the conclusion of the exchange of letters complementing the Agreement of 20 October 1987 between the Community and the Republic of Argentina under GATT Article XXIV.6, following the accession of Spain and Portugal; pursuant thereto, the Community will continue to ensure a minimum annual level of imports of corn and sorghum into Spain until 31 December 1991, in accordance with the 1987 Agreement. This extension of the Agreement is without prejudice to any legal interpretations of Article XXIV by either party.

ECSC

The Representatives of the Governments of the Member States of the European Coal and Steel Community, meeting within the Council, adopted the Decision opening import possibilities for steel and pig iron products from Central and Eastern Europe for 1991.

Relations with the Overseas Countries and Territories

The Council adopted the Decision on the apportionment of the unexpended balance of STABEX funds among the Overseas Countries and Territories.

Pursuant to this Decision, the sum of ECU 583 984 will be paid to the territory of French Polynesia and the sum of ECU 160 016 to the Falkland Islands as their respective shares of the unexpended balance of the STABEX resources made available during the period of validity of Decision 86/283/EEC on the association of overseas countries and territories with the Community.

Decisions in the area of agricultural policy

The Council adopted Directives

- amending Directive 86/466/EEC concerning the Community list of less-favoured farming areas within the meaning of Directive 75/268/EEC (Spain)

- amending Directive 85/350/EEC concerning the Community list of less-favoured farming areas within the meaning of Directive 75/268/EEC (Ireland).

These amendments extend the Community lists of less-favoured farming areas in Spain and Ireland. As far as Spain is concerned, the extension adopted is 1 223 981 ha, which increases the proportion of less-favoured areas in Spain to 67.5% of the total utilized agricultural area of the country.

In the case of Ireland, the increase is 755 898 ha classified as less-favoured areas, which increases the proportion of such areas in Ireland to 71,25% of the total utilized agricultural area of the country.

The Council adopted Regulations

- amending Regulation (EEC) No 3677/89 with regard to the total alcoholic strength by volume of certain quality wines imported from Hungary.

  The purpose of the amendment is to extend by one year, until 31 August 1992, the expiry date of the waiver granted in the case of certain quality wines originating in Hungary as regards their total alcoholic strength, which exceeds the maximum strength by volume of 15% normally permitted by Community rules. This extension should enable the overall wine sector agreement currently under discussion between the Community and Hungary to be concluded.

- amending for the fourth time Regulation (EEC) No 2390/89 laying down general rules for the import of wines, grape juice and grape must.

  The purpose of the amendment is to extend by three months, until 31 October 1991, the derogatory rules which introduce a degree of flexibility regarding the certificates of origin and analysis reports to be supplied by the United States on condition, however, that the United States offers specific guarantees accepted by the Community.

- amending for the fifth time Regulation (EEC) No 1873/84 authorizing the offer or disposal for direct consumption of certain imported wines which may have undergone oenological processes not provided for in Regulation (EEC) No 822/87.

  The purpose of the amendment is to extend by three months, until 31 October 1991, the waiver granted in the case of wines originating in the United States as regards the application of certain oenological practices allowed in the United States but not allowed in the Community.

These two three-month extensions should be sufficient to enable the Community and the United Stats to complete their negotiations, now at the final stage, for the conclusion of a wine sector agreement.

The Council also adopted a Directive laying down the health conditions for the production and placing on the market of fishery products.

Political agreement was reached on this Directive at the Agricultural Council meeting on 26 and 27 June 1991 (See Press Release 7144/91 Presse 121).

Appointments

On a proposal from the Belgian Government, the Council appointed Mr Ronald JANSSENS a member of the Economic and Social Committee in place of Mr François WILLEKENS, whose membership of the Committee has become incompatible with his employment, for the remainder of the latter's term of office, which runs until 20 September 1994.

The Council also replaced a member and two alternate members of the Advisory Committee on Safety, Hygiene and Health Protection at Work.