



**COUNCIL OF  
THE EUROPEAN UNION**

**Brussels, 1 August 2007**

**10155/07**

**LIMITE**

<b>PV/CONS</b>	<b>30</b>
<b>SOC</b>	<b>237</b>
<b>SAN</b>	<b>118</b>
<b>CONSOM</b>	<b>78</b>

**DRAFT MINUTES <sup>1</sup>**

---

Subject : **2803rd** meeting of the Council of the European Union (**EMPLOYMENT, SOCIAL POLICY, HEALTH and CONSUMER AFFAIRS**), held in Brussels on 30 and 31 May 2007

---

---

<sup>1</sup> Information relating to the final adoption of Council acts which may be released to the public may be found in Addendum 1 to these minutes.

## CONTENTS

### Page

1.	Adoption of the agenda.....	4
2	Approval of the list of "A" items.....	4
3.	Active ageing.....	4
4.	"Good work" Draft Council Resolution on a new Community strategy 2007-2012 on health and safety at work.....	5
5.	Proposal for a Regulation of the European Parliament and of the Council laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems.....	5
6.	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of Annex XI.....	6
7.	Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (Miscellaneous amendments 2006).....	6
8.	Proposal for a Directive of the European Parliament and of the Council on minimum requirements for enhancing worker mobility by improving the vesting and preservation of supplementary pension rights.....	7
9.	Draft conclusions of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, on the importance of family-friendly policies in Europe and the establishment of an Alliance for Families.....	8
10.	Implementation of the Beijing Platform for Action.....	9
11.	Social Services of General Interest.....	9
12.	Draft Council Resolution on EU Consumer Policy Strategy 2007-2013.....	9
13.	Food improvement agents package.....	10
14.	Health promotion by means of nutrition and physical activity.....	11
15.	Proposal for a Regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004.....	11

16.	Combating HIV/AIDS within the European Union and in the neighbouring countries.....	12
17.	Health Care across Europe - Community framework on health services.....	13
18.	Proposal for a Council Recommendation on the prevention of injury and the promotion of safety .....	14
19.	Commission Green Paper "Towards a Europe free from tobacco smoke: policy options at EU level" .....	14
20.	Any other business	
	(a) Information on Presidency conferences .....	15
	(b) Social Partners' Framework agreement on harassment and violence at work .....	15
	(c) Communication from the Commission: Promoting solidarity between the generations .....	16
	(d) Social aspects of human trafficking .....	16
	(e) Presidency Conference "Challenges and Opportunities in a Digitalised World. The Role of Consumer Policy" .....	16
	(f) Second Programme of Community action in the field of Health (2007-2013).....	16
	(g) Presidency Conferences on Health.....	16
	(h) Framework Convention on Tobacco Control.....	17
	(i) International Health Regulations.....	17
	(j) European Strategy on Diet, Physical Activity and Health .....	17
	(k) Communication from the Commission on improving the mental health of the population.....	17
	(l) Communication from the Commission on organ donation and transplantation .....	18
	(m) Health Security Committee and related matters .....	18
	(n) Proposal for a Directive of the European Parliament and of the Council amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives .....	18
	(o) Work programme of the incoming Presidency .....	18
ANNEX	.....	19

o

o

o

1. **Adoption of the agenda**

9714/07 OJ/CONS 29 SOC 210 SAN 100 CONSOM 63

The Council adopted the above agenda.

2. **Approval of the list of "A" items**

10005/06 PTS A 23

+ ADD 1

The Council approved the list of "A" items contained in 10005/07 + ADD 1.

Information relating to items 7 and 8 on the list is set out in Addendum 1 to these minutes.

The documents in items 2 and 3 should read as follows:

**Item 2:** 7344/3/07 REV 3 SOC 97  
**+ REV 4 (bg, ro)**

**Item 3:** 9040/1/07 **REV 1** AVIATION 78 COEST 145 NIS 122 RELEX 316  
9142/07 AVIATION 80 COEST 149 NIS 125 RELEX 293  
+ COR 1  
+ COR 2 (fi)  
+ COR 3 (cs)  
+ COR 4  
**+ COR 5 (cs)**

3. **Active ageing**

- Endorsement of joint Employment Committee/Social Protection Committee opinion  
9269/07 SOC 182 ECOFIN 185  
+ REV 1 (mt)  
+ REV 2 (hu)

The Council endorsed the joint Opinion of the Employment Committee and the Social Protection Committee as set out in 9269/07 + REV 1 (mt) + REV 2 (hu).

4. **"Good Work"**

**Draft Council Resolution on a new Community strategy 2007-2012 on health and safety at work**

- Policy debate and adoption
  - 6775/07 SOC 77
    - + REV 1 (da)
  - 9353/07 SOC 194
    - + REV 1 (de)
    - + REV 1 COR 1 (de)
  - 9797/07 SOC 220

The Council held a policy debate on the basis of a set of questions prepared by the Presidency as set out in 9797/07 and adopted the Resolution as set out in 9353/07 + REV 1 (de) + REV 1 COR 1 (de). The Council decided, moreover, to publish the Resolution in the Official Journal following Legal-Linguistic fine-tuning.

5. **Proposal for a Regulation of the European Parliament and of the Council laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems**

(a) **Title III, Chapter 1 (Sickness, maternity and equivalent paternity benefits)**

(b) **Title IV, Chapter 1 (Financial provisions)**

- Partial general approach  
(Public deliberation, pursuant to Article 8(1)(c) CRP)
  - 5896/06 SOC 44 CODEC 93
  - 9747/07 SOC 213 CODEC 540
  - 9752/07 SOC 215 CODEC 546

The Council:

- reached a partial general approach on Title III, Chapter 1 (sickness, maternity and equivalent paternity benefits) and on Title IV, Chapter 1 (Financial provisions) as set out in 9752/07 and 9747/07 respectively ;

- decided to enter in its Minutes the two statements by the Spanish delegation as set out in the Annex.

6. **Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 883/2004 on the coordination of social security systems, and determining the content of Annex XI**

- (a) Amendments to Regulation (EC) No 883/2004
- (b) Annex VIII
- (c) Parts of the proposal determining the content of Annex XI which relate to Title III, Chapter 1, of the Proposal for a Regulation of the European Parliament and of the Council laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems
  - Partial general approach  
(Public deliberation, pursuant to Article 8(1)(c) CRP)  
5672/06 SOC 28 CODEC 66  
9759/07 SOC 216 CODEC 550

The Council reached a partial general approach on parts of the draft Regulation as set out in 9754/07.

7. **Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EEC) No 1408/71 on the application of social security schemes to employed persons, to self-employed persons and to members of their families moving within the Community (Miscellaneous amendments 2006)**

- General approach  
(Public deliberation, pursuant to Article 8(1)(c) CRP)  
8178/07 SOC 129 CODEC 319  
9351/1/07 SOC 193 CODEC 476 REV 1  
+ COR 1

The Council reached a general approach on the draft Regulation as set out in 9351/1/07 REV 1 + COR 1.

8. **Proposal for a Directive of the European Parliament and of the Council on minimum requirements for enhancing worker mobility by improving the vesting and preservation of supplementary pension rights**

- General approach  
(Public deliberation, pursuant to Article 8(1)(b) CRP)
  - 13686/05 SOC 412 ECOFIN 324 CODEC 933
    - + REV 1 (de, en)
  - 9761/1/07 SOC 217 ECOFIN 218 CODEC 551 REV 1
    - + COR 1
  - 9763/07 SOC 218 ECOFIN 219 CODEC 552
    - + COR 1

The Council endeavoured to reach a general approach on the proposal, pending the European Parliament's Opinion in first reading, but was unable to reach the required unanimity.

The Netherlands delegation maintained a general reservation. Underlining the potentially uneven impact of the measures proposed, which would mainly affect countries (such as the Netherlands) where supplementary pension schemes are common, this delegation expressed its concern that, in its current form, the draft Directive would promote neither worker mobility nor the establishment of supplementary pension schemes, and that abiding legal uncertainties could expose pension funds to serious financial risk. This delegation, moreover, regretted the substantial delay envisaged before the proposed provisions would take effect. However, the Netherlands did not exclude the possibility of negotiations continuing on the proposal.

The French delegation lifted the general reservation it had maintained pending the formation of its new government, and also indicated that it was no longer seeking an exemption for schemes intended for managing executives (see Article 2(3)(b) and Recital 5fb).

Whilst expressing concern that the text currently on the table weakened the provisions contained in the Commission's original proposal, the Belgian delegation nevertheless expressed regret that it was not possible to arrive at an agreement in Council.

The Finnish delegation called for continued efforts to reach an agreement, with a view to protecting the rights of mobile workers. Recalling that it was prepared to accept a compromise without provisions on transferability, the Italian delegation also expressed regret that no agreement could be found, and called for further efforts to break the deadlock. The Greek delegation echoed this plea, and made the point that a transitional period was inevitable.

The President concluded that the discussion on this proposal would continue at a later date on the basis of the European Parliament's Opinion in first reading. Underlining the importance of the proposal in the context of flexicurity, the Commission pledged its active support in the search for a compromise between the Council and the European Parliament.

9. **Draft conclusions of the Council and of the Representatives of the Governments of the Member States, meeting within the Council, on the importance of family-friendly policies in Europe and the establishment of an Alliance for Families**

- Adoption and exchange of views  
(Public debate, pursuant to Article 8(3) CRP, [proposed by the Presidency])  
8913/07 SOC 162  
9317/1/07 SOC 185 REV 1

The Council held a policy debate on the basis of a set of questions prepared by the Presidency as set out in 8913/07 during which a large majority of the delegations expressed their support for the German Presidency's initiative to set-up an Alliance for Families.



Furthermore, the Council adopted the Conclusions set out in 9317/1/07 SOC 185 REV 1 and decided to publish them in the Official Journal.

**10. Implementation of the Beijing Platform for Action**

- Adoption of Council conclusions  
9152/07 SOC 175
  - + COR 1 (fr)
  - + REV 1 (fi)
  - + REV 2 (pt)
  - + ADD 1

The Council adopted the conclusions as set out in 9152/07 + COR 1 (fr) + REV 1 (fi) + REV 2 (pt) and took note of the Presidency report presenting indicators for the follow-up of the Beijing Platform for Action in the critical area of "the Education and Training of Women", as contained in 9152/07 ADD 1.

**11. Social Services of General Interest**

- Oral progress report by the Social Protection Committee Chair

The Council took note of the oral report by the Chair of the Social Protection Committee.

**12. Draft Council Resolution on EU Consumer Policy Strategy 2007-2013**

- Adoption  
(Public debate, pursuant to Article 8(3) CRP [proposed by the Presidency])  
9542/07 CONSOM 59 MI 121 JUSTCIV 134

The Council adopted the draft resolution as set out in 9542/07 and agreed to its publication in the Official Journal.

### 13. Food improvement agents package

- (a) **Proposal for a Regulation of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings**
  - General approach  
(Public deliberation, pursuant to Article 8(1)(c) CRP)  
9536/07 DENLEG 35 CODEC 515 ADD 1
  
- (b) **Proposal for a Regulation of the European Parliament and of the Council on food additives**
  - General approach  
(Public deliberation, pursuant to Article 8(1)(c) CRP)  
9536/07 DENLEG 35 CODEC 515 ADD 2
  
- (c) **Proposal for a Regulation of the European Parliament and of the Council on food enzymes and amending Council Directive 83/417/EEC, Council Regulation (EC) No 1493/1999, Directive 2000/13/EC, Council Directive 2001/112/EC and Regulation (EC) No 258/97 of the European Parliament and of the Council**
  - General approach  
(Public deliberation, pursuant to Article 8(1)(c) CRP)  
9536/07 DENLEG 35 CODEC 515 ADD 3
  
- (d) **Proposal for a Regulation of the European Parliament and of the Council on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1576/89, Council Regulation (EEC) No 1601/91, Regulation (EC) No 2232/96 and Directive 2000/13/EC**
  - State of play  
(Public deliberation, pursuant to Article 8(1)(c) CRP)  
9536/07 DENLEG 35 CODEC 515 ADD 4

The Council agreed three general approaches as set out in 9536/07 ADD 1 (for the proposal on common authorisation procedure), 9536/07 ADD 2 (for the proposal on food additives) and 9536/07 ADD 3 (for the proposal on enzymes) and took note of the progress report concerning the proposal on flavourings contained in 9536/07 ADD 4.

**14. Health promotion by means of nutrition and physical activity**

- Adoption of Council conclusions  
(Public debate, pursuant to Article 8(3) CRP [proposed by the Presidency])  
9363/07 SAN 89

The Council held a policy debate and recognised the importance of strategic and concrete actions to promote healthy eating and physical activity. Obesity is one of the biggest health threats in the EU that causes serious diseases and has negative economic and social consequences. Therefore, a comprehensive approach should be applied to address this issue. The creation of a High Level Group to discuss further actions was suggested by the Commission.

Delegations reported on the actions taken at national level to fight obesity and promote healthy lifestyles. The incoming Portuguese and Slovenian Presidencies stated their commitment to keeping this issue high on the Council's agenda.

The Council adopted the conclusions set out in 9363/07.

**15. Proposal for a Regulation of the European Parliament and of the Council on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004**

- Political agreement  
(Public deliberation, pursuant to Article 8(1) (c) CRP)  
15023/05 ECO 147 SAN 192 CODEC 1100  
9756/07 MI 129 ECO 74 SAN 101 CODEC 549 + COR 1 (mt)

The Council unanimously approved the agreement reached by the Permanent Representatives Committee on 16 May 2007 on the text of the draft Regulation set out in the Annex to 9756/07 and mandated the Presidency to communicate the Council's approval of the text to the European Parliament, thus confirming agreement at first reading. The Netherlands, Danish and Maltese delegations made statements to these minutes (see Annex).

**16. Combating HIV/AIDS within the European Union and in the neighbouring countries**

- Policy debate / Adoption of Council conclusions  
(Public debate, pursuant to Article 8(3) CRP [proposed by the Presidency])  
15925/05 SAN 218  
7977/07 SAN 58  
9537/07 SAN 96

The Council held a policy debate based on the questions set out in 7977/07.

Responding to the first question, delegations reported on the active involvement of civil society, including people with HIV, in the fight against this pandemic and the defence of human rights in their countries. They shared the opinion that prevention, especially among young people and other vulnerable groups, is of key importance in fighting the pandemic. Approaches to intensified civil society involvement in the Member States include:

- the preparation of national programmes for the prevention and fight against HIV/AIDS;
- better coordination among different policy sectors and levels of authorities;
- cooperation with the media and industry; and
- the organisation of conferences as well as education, training and information campaigns to reduce social stigma.

The Council recognised the importance of a comprehensive approach to address the HIV/AIDS problem. Actions at EU level should include:

- an accurate identification and study of the problem;
- the creation of a network of measures and actions to solve it;
- the use of EU funds; and
- the enhancement of civil society participation.

Responding to the second question, the Council confirmed that access to antiretroviral treatment was a complex issue and the prices of retroviral drugs posed an obstacle to the sustainability of treatment and to the access to such drugs in some parts of Europe.

Constructive dialogue and the involvement of the pharmaceutical industry was regarded as one of the major means of increasing access and reducing prices. Cooperation among the Member States and the EU institutions, as well as further investment in research in order to develop new medicines, would contribute to tackling the problem of access to treatment.

The Council adopted the conclusions set out in 9537/07.

**17. Health Care across Europe - Community framework on health services**

- Exchange of views / Adoption of Council conclusions  
(Public debate, pursuant to Article 8(3) CRP [proposed by the Presidency])  
9540/07 SAN 97 SOC 202 MI 120  
+ COR 1

The Council held an exchange of views on a Community framework on health services and adopted the draft Council conclusions set out in 9540/07.

The Commission announced that it would submit a legislative proposal on a possible Community framework for health services by the end of 2007. The Council encouraged the Commission to take into account the Council Conclusions of 1 June 2006 containing a statement on the common values and principles in EU health systems.

In drawing up the new legal framework, the existing regulation on the coordination of social security systems <sup>2</sup> should be taken into account in order to avoid duplication and inconsistency.

**18. Proposal for a Council Recommendation on the prevention of injury and the promotion of safety**

- Adoption
  - 10938/06 SAN 184 SOC 334
  - 9476/07 SAN 92 SOC 198
  - 8344/07 SAN 64 SOC 135
    - + COR 1
    - + COR 2 (fr)
    - + COR 3 (en)

The Council adopted the recommendation set out in 8344/07 and agreed to its publication in the Official Journal.

**19. Commission Green Paper "Towards a Europe free from tobacco smoke: policy options at EU level"**

- Exchange of views  
(Public debate, pursuant to Article 8(3) CRP [proposed by the Presidency])
  - 5899/07 SAN 17
  - 9362/07 SAN 88

The Council, based on the question set out in 9362/07, held an exchange of views on the policy options at EU level on tobacco-smoke free environments. It welcomed the Commission's Green Paper and stressed the need for Community guidance to further promote tobacco-smoke free environments at EU level, as well as Community support for and coordination of national measures.

---

<sup>2</sup> Regulation (EC) No 883/2004 of the European Parliament and of the Council of 29 April 2004 on the coordination of social security systems (OJ L 166, 30.4.2004, p. 1. Corrected version in OJ L 200, 7.6.2004, p. 1).

The Council shared the view that adoption of specific legislation at Member State level would be the most appropriate tool to tackle this issue, as this public health measure fell within the competence of Member States. The Council also considered that a recommendation would be appropriate to encourage the Member States to enact specific "smoke free" legislation. This should be complemented by prevention, information and education campaigns. The increased public support for anti-smoking policies demonstrates the effectiveness of the measures taken at national level.

## **20. Any Other Business**

### **(a) Information on Presidency conferences**

- (i) Euromed Conference (Berlin, 16 March 2007)
- (ii) Quality of Work (Berlin, 2-3 May 2007)
- (iii) Sixth European Meeting of People Experiencing Poverty (Brussels, 4-5 May 2007)
- (iv) Meeting of G-8 Labour Ministers (Dresden, 5-8 May 2007)
- (v) Informal Meeting of Ministers for Gender Equality and Family (Bad Pyrmont, 15-16 May 2007)  
9820/07 SOC 222
- (vi) UN Commission on the Status of Women, 51st Session (New York, 26 February - 9 March 2007)  
9822/07 SOC 223
- (vii) European Congress "Demographic Change as Opportunity: the Economic Potential of the Elderly" (Berlin, 17-18 April 2007)  
9823/07 SOC 224

The Council took note of the information provided by the Presidency.

### **(b) Social Partners' Framework agreement on harassment and violence at work**

- Information from the Commission  
9967/07 SOC 233

The Council took note of the written information provided by the Commission.

**(c) Communication from the Commission: Promoting solidarity between the generations**

- Presentation by the Commission  
9717/07 SOC 211

The Council took note of the written information provided by the Commission.

**(d) Social aspects of human trafficking**

- Information from the Danish delegation  
9824/07 SOC 225

The Council took note of the information provided by the Danish delegation.

**(e) Presidency Conference "Challenges and Opportunities in a Digitalised World. The Role of Consumer Policy"**

- Information from the Presidency  
9412/07 CONSOM 57

The Council took note of the information from the Presidency.

**(f) Second Programme of Community action in the field of Health (2007-2013)**

- Information from the Presidency  
9830/07 SAN 104 CODEC 565 IM 132

The Council took note of the information on the state of play with regard to the above-mentioned legislative proposal.

**(g) Presidency Conferences on Health**

- Information from the Presidency  
9831/07 SAN 105 MI 135 ECO 76 COMPET 158

The Council took note of the above information.



**(h) Framework Convention on Tobacco Control**

- Oral information from the Presidency
- Information from the Commission  
9832/07 SAN 106

The Council took note of the above information.

**(i) International Health Regulations**

- Oral information from the Presidency
- Information from the Commission  
9833/07 SAN 107

The Council took note of the information on the state of play with regard to the implementation of the International Health Regulations.

**(j) European Strategy on Diet, Physical Activity and Health**

- Oral information from the Commission

The Council took note of the adoption by the Commission of the White Paper on: A Strategy for Europe on Nutrition, Overweight and Obesity related health issues.

**(k) Communication from the Commission on improving the mental health of the population**

- Information from the Commission  
9836/07 SAN 109

The Council took note of the above information.

- (l) **Communication from the Commission on organ donation and transplantation**  
- Oral information from the Commission

The Council noted that the above Communication had been adopted by the Commission on 30 May 2007.

- (m) **Health Security Committee and related matters**  
- Information from the Commission  
9839/07 SAN 111

The Council took note of the above information.

- (n) **Proposal for a Directive of the European Parliament and of the Council amending Council Directives 90/385/EEC and 93/42/EEC and Directive 98/8/EC of the European Parliament and the Council as regards the review of the medical device directives**  
- Information from the Presidency on the outcome of the negotiations with the European Parliament  
9819/07 MI 131 ECO 75 SAN 103 CODEC 561

The Council took note of the above information.

- (o) **Work programme of the incoming Presidency**  
- Information from the Portuguese delegation

The Council took note of the above information.

---

STATEMENTS TO THE COUNCIL MINUTES

Ad item 5

Statements by the Spanish delegation

1. Article 25(6), (7) and 7(a)

"Spain considers that Article 25(6), (7) and (7a), of the Proposal for a Regulation of the European Parliament and of the Council laying down the procedure for implementing Regulation (EC) No 883/2004 on the coordination of social security systems is related to Article 19 of Regulation (EC) No 883/2004 and has to be understood and interpreted in this way. Therefore, bearing in mind that the Spanish Public Health Services, according to Spanish legislation, do not refund, except in exceptional cases of vital emergency, treatments provided by private health institutions, the Spanish Social Security Administrations will apply paragraph 7a) and will not be able to provide national reimbursement rates in these cases.

For treatments provided by doctors and hospitals depending on public institutions, taking into account that the sharing of costs by the insured person does not exist, the invoices that are issued by public doctors and hospitals correspond to the actual amount referred to in Article 61 of the Regulation laying down the procedure for implementing Regulation (EC) No 883/2004."

2. Article 29

"Spain considers that Article 29 of this Regulation should have included paragraph 2 of the Ruling on the case C-50/05, Maija T I Nikula that establishes: *"However, Article 39 EC precludes the amount of pensions received from institutions of another Member State from being taken into account if contributions have already been paid in that other State out of income from work received in that State. It is for the persons concerned to prove that the earlier contributions were in fact paid."*

Trying to obtain the necessary consensus and unanimity, the Spanish Delegation can accept not including a specific paragraph in Article 29 which would refer to paragraph 2 of this ruling, convinced that, in any case, the content of this judgment will continue to be applicable and therefore institutions and beneficiaries could require its implementation. In this sense, the Spanish Administration reserves its right to support the claims of the eventual beneficiaries of this ruling. Furthermore, the Spanish Administration is committed, in the event that a Member State applies Article 30 of Regulation (EC) No 883/2004 and consequently deducts contributions from the Spanish pensions in order to finance their sickness insurance, to reach agreements and arrangements with this Member State for assuming and transferring directly the amounts of contributions. The intention of the Spanish Administration is to avoid financial losses to the detriment of migrant workers who are beneficiaries of Spanish pensions and who reside in the territory of other Member States which provide for the collection of contributions on these pensions."

## **Ad item 15**

### **1. Statement by the Netherlands and Danish delegations**

"The Netherlands and Denmark welcome the proposal for a Regulation on advanced therapy medicinal products. Specially tailored and harmonised rules for this product category will improve the accessibility and safety of these technologically advanced products.

This Regulation lays down that all combinations of medical devices with viable cells will be classified as advanced therapy medicinal products. This will mean that the nature of the material will determine which product regime is applicable. The Netherlands and Denmark regret this.

The Netherlands and Denmark have persistently emphasised the importance of the principal mode of action for the intended purpose as the guiding principle which should determine which regulatory regime is applicable to a specific product. This guiding principle has proven its value over the past decades as the cornerstone of the delineation between several product categories, such as pharmaceuticals, medical devices, cosmetics and foodstuffs.

One of the most important trends in product development is the combination of more than one technology into one product, also known as converging technologies. As a result, the number of products which it will be difficult to classify into a specific regulatory framework will increase substantially. A consistent, clear and future-proof criterion for assigning products to a regulatory structure is therefore necessary.

The Netherlands and Denmark would like to stress that the approach chosen in the case of combinations of medical devices with viable cells and/or tissues is an exception to the well-established approach which exists today in the medicinal and medical device sector. The principal mode of action for the intended purpose should remain the guiding principle in all other future cases."

## **2. Statement by the Maltese delegation**

"Malta acknowledges the importance of having advanced therapy medicinal products regulated under a specific regulatory framework, whereby the products will be evaluated by the European Medicines Agency and placed on the market through the centralised procedure.

Notwithstanding, Malta holds that medicinal products that contain or are derived from human embryonic and foetal cells, primordial germ cells or cells derived from those cells should not have been included within the scope of the Advanced Therapy Regulation. Malta firmly maintains that it does not approve of any form of human embryonic stem cell extraction from live, even frozen embryos.

More specifically, Malta does not approve of experimentation on existing cell clone lines of human embryonic stem cells available on the market, by reason of complicity. Malta, however, finds no ethical problem when adult stem cells, including cord blood stem cells, are used for the production of medicinal products.

Nevertheless, Malta notes that Article 28(2) of the Advanced Therapy Regulation amending Directive 2001/83/EC affirms that the latter Directive and all Regulations referred to therein shall not affect the application of national legislation prohibiting or restricting the use of any specific type of human or animal cells, or the sale, supply or use of medicinal products containing, consisting of or derived from these cells."

---

---

This paper represents the views of its author on the subject. These views have not been adopted or in any way approved by the Commission and should not be relied upon as a statement of the Commission's or Health & Consumer Protection DG's views. The European Commission does not guarantee the accuracy of the data included in this paper, nor does it accept responsibility for any use made thereof.