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NOTE

from:	General Secretariat
to:	Working Party on Public Health
No Cion prop.:	16796/11 SAN 241 PHARM 4 MI 562 CADREFIN 128 CODEC 2002
Subject:	Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on establishing a Health for Growth Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020

Delegations will find attached the Presidency compromise text for Chapter I and II. This text will be discussed at the Working Party meeting on Public Health on 2 April 2012.

* * *

The text in the attachment is marked as follows:

~~Strikethrough~~	Deletions of the text of the Commission's proposal
bold italics	Additions to the text of the Commission's proposal

ANNEX

Presidency compromise text

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on

establishing a Health for Growth Programme, the third multi-annual programme of E*uropean* U*nion* action in the field of health for the period 2014-2020 *and repealing Decision No 1350/2077/EC*

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article168 (5) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

Whereas:

…

(7) Innovation in health***,*** in terms of products and services, and ***in*** the organisation and provision of care, has the potential to enhance the quality of care to patients and respond to unmet needs, while also improving ~~the~~ ***its*** cost-efficiency and sustainability of care. Therefore, the Programme should facilitate the uptake of innovation in healthcare ***consistant with the common values and principles in European Union Health Systems as set out in the Council conclusions of June 2006[3]***.

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1 OJ C , , p. .

2 OJ C , , p. .

3 OJ C 146 of 22 June 2006, p. 1

HAVE ADOPTED THIS REGULATION:

Chapter I

General provisions

Article 1

Establishment of the Programme

This Regulation establishes a ***Health and Growth Programme("the Programme"), the*** third multi-annual programme of Union action in the field of health~~, called Health for Growth Programme,~~ covering the period from 1 January 2014 to 31 December 2020 ~~(hereinafter referred to as "the Programme")~~.

Article 2

General objectives

The general objectives of the ~~Health for Growth~~ Programme shall be to ***complement, support and add value to the policies of*** ~~work with~~ the Member States to ***improve the health of EU citizens and reduce health inequalities by promoting health,*** encourag***ing*** ~~e~~ innovation in healthcare and increas***ing*** ~~e~~ the sustainability of health systems~~, to improve the health of the EU citizens~~ and protect***ing Union citizens*** ~~them~~ from ***serious*** cross-border health threats.

Chapter II

Objectives and actions

Article 3

Specific objectives and indicators

The general objectives referred to in Article 2 shall be pursued through the following specific objectives:

(***1*** ~~3~~) To identify, disseminate and promote the up-take of ~~validated best~~ ***good*** practices for cost-effective prevention measure***s and to foster supportive environments for healthy lifestyles*** by addressing the key ***health determinants*** ~~risk factors~~, ***especially*** ~~namely~~ ***use of tobacco*** ~~smoking~~, ***harmful use*** ~~abuse~~ of alcohol***, unhealthy eating habits and physical inactivity*** ~~and obesity~~, as well as HIV/AIDS, with a focus on the ***cross-border*** dimension, in order to prevent diseases and promote good health.

This objective will be measured in particular through the increase ~~of~~ ***in the*** number of Member States involved in promoting good health and preventing diseases, using the ~~validated best~~ ***good*** practices.

(***2***~~4~~) To ***identify and*** develop common approaches and ***promote their implementation*** ~~demonstrate their value~~ for better preparedness and coordination in health emergencies in order to protect citizens from cross-border health threats.

This objective will be measured in particular through the increase of number of Member States integrating the ~~developed~~ common approaches in the design of their preparedness plans.

(***3***~~1~~) To ***identify and*** develop ~~common~~ tools and mechanisms at ~~EU~~ ***Union*** level to address shortages of resources, both human and financial, and to facilitate ***the voluntary*** up-take of innovation in healthcare ***and in public health as well as to support public health capacity building*** in order to contribute to innovative***, efficient*** and sustainable health systems.

This objective will be measured in particular through the increase ***in the advice produced and the*** ~~of~~ number of Member States using the ~~developed~~ tools and mechanisms ***identified*** ~~and pieces of advice~~.

(***4***~~2~~) To increase access to medical expertise and information for specific conditions also beyond national borders, and to develop ~~shared~~ solutions and***/or*** guidelines ***for the*** ~~to~~ improve***ment of*** healthcare quality and patient safety in order to ***facilitate*** ~~increase~~ access to better and safer healthcare for ~~EU~~ ***Union*** citizens.

This objective will be measured in particular through the increase ***in the*** ~~of~~ number of health professionals using the expertise gathered through the European Reference Networks in the context of Directive 2011/24/EU ***of the European Parliament and of the Council of 9 March 2011***[4] on the application of patients' rights in cross-border healthcare (hereinafter referred to as "the European Reference Networks"); the increase ***in the*** ~~of~~ number of patients ~~using~~ ***benefiting from*** th***is expertise*** ~~ese networks~~; and the increase ***in the*** ~~of~~ number of Member States using the developed ***solutions and*** guidelines.

Article 4

Eligible actions

The objectives referred to in Article 3 shall be achieved through the actions listed ***in annex I*** ~~below~~ and according to the priorities set out in the work programme referred to in Article 11 of this Regulation. ***An indicative list of the relevant legislation is provided in Annex II to this Regulation***

~~(1) Contributing to innovative and sustainable health systems:~~

~~1.1. Develop EU cooperation on Health Technology Assessment in the context of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare;~~

~~– 1.2. Promote the uptake of health innovation and e-Health by increasing the interoperability of e-Health applications;~~

~~1.3. Support the sustainability of EU health workforce by promoting effective forecasting and planning and efficient recruitment and retention strategies;~~

~~– 1.4. Provide expertise to assist Member States undertaking health systems reforms;~~

~~– 1.5 Support to the European Innovation Partnership on Active and Healthy Ageing, a pilot project under Europe 2020 flagship initiative Innovation Union[5];~~

~~1.6 Actions required by or contributing to the objectives of EU legislation in the fields of medical devices as well as e-Health and Health Technology Assessment provisions in legislation on cross border healthcare;~~

~~1.7 Foster a health knowledge system, including Scientific Committees, to contribute to evidence-based decision making.~~

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[4] ***OJ L 88, 4.4.2011, p.45***

[5] ~~COM (2010) 546 final~~

~~(2) Increasing access to better and safer healthcare for citizens:~~

- ~~2.1. Set up accreditation and support European Reference Networks;~~
- ~~2.2. Support action on rare diseases including creation of European Reference Networks (in accordance with 2.1), information and registries based on the common criteria for accreditation;~~
- ~~2.3. Strengthen collaboration on patient safety and quality of healthcare, by increasing the availability of information to patients, exchange of best practices and development of guidelines; support action on chronic diseases care and research including development of European guidelines;~~
- ~~2.4. Develop guidelines to improve the prudent use of antimicrobials in human medicine and reduce the practices that increase antimicrobial resistance;~~
- ~~2.5. Actions required by or contributing to the objectives of EU legislation in the fields of tissues and cells, blood, organs, patients' rights in cross-border healthcare and medicinal products;~~
- ~~2.6. Foster a health knowledge system, to contribute to evidence-based decision making.~~

~~(3) Promoting good health and preventing diseases:~~

- ~~3.1 Exchange best practices on key health issues such as smoking prevention, abuse of alcohol and obesity;~~
- ~~3.2. Supporting the prevention of chronic diseases including cancer, by sharing knowledge and best practice and developing joint activities;~~
- ~~3.3. Actions required by or contributing to the objectives of EU legislation in the fields of tobacco products and advertisement;~~
- ~~3.4. Foster a health knowledge system, to contribute to evidence-based decision making.~~

~~(4) Protecting citizens from cross border health threats:~~

- ~~4.1. Strengthen preparedness and response for serious cross border health threats;~~
- ~~4.2. Improve risk assessment capacity by providing additional capacities for scientific expertise and map existing assessments;~~

– 4.3. Support capacity building against health threats in Member States by *inter alia* developing preparedness and response planning and coordination, common approaches to vaccination, developing guidelines and mechanisms for joint procurement of medical countermeasures;

– 4.4. Actions required by or contributing to the objectives of EU legislation in the fields of communicable diseases and other health threats;

– 4.5. Foster a health knowledge system to contribute to evidence-based decision making.

A more detailed description of the content those actions may have is included in Annex I. An indicative list of the relevant legislation is provided in Annex II to this Regulation.

ANNEX I

Types of actions

1~~3~~. ***Promoting good health and preventing diseases:*** **Identifying, disseminating and promoting up-take of *good practices* ~~validated best practices~~ for cost-effective prevention measures by addressing the key *health determinants* ~~risk factors~~, *especially*~~namely~~ *tobacco use*~~smoking~~, *harmful use* ~~abuse~~ of alcohol, *unhealthy eating habits* and *physical inactivity*~~obesity~~, as well as HIV/AIDS, with a focus on the cross-border dimension.~~, in order to prevent diseases and promote good health~~**

1~~3~~.1. Cost-effective promotion and prevention measures***,*** ~~: this will~~ includ***ing***~~e~~ actions towards ***fostering supportive environments for healthy lifestyles and addressing health determinants, especially use of tobacco, harmful use of alcohol, unhealthy eating habits and physical inactivity*** ~~the setting up of pan-European networks and partnerships engaging wide range of actors in communication and awareness raising actions on key health issues such as smoking prevention, abuse of alcohol, addressing obesity~~ with a focus on the cross-border dimension and on Member States with no or little action on these issues.

1~~3~~.2. ~~Chronic diseases: s~~***S***upport ***the prevention of chronic diseases and conditions through*** European cooperation and networking on preventing and improving the response to chronic diseases including cancer, by sharing knowledge, good practice and developing joint activities on prevention. ~~Cancer: f~~***F***ollow-up work ***on cancer*** already undertaken; set up a European cancer information system with comparable data; support cancer screening, including voluntary accreditation mechanisms; support the development of European guidelines for prevention where major inequalities exist.

1.3 Promote the implementation of the "health in all policies" principle in national and EU policies.

1~~3~~.~~3~~4. Actions required by or contributing to the implementation of Union legislation in the fields of tobacco products and advertisement. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

1~~3~~.4~~5~~. Fostering a health ***information and*** knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide dissemination of the results of the Programme.

2~~4~~. Protecting citizens from serious cross border health threats: **Developing common approaches and *promoting their implementation* ~~demonstrating their value~~ for better preparedness and coordination in health emergencies ~~in order to protect citizens from cross-border health threats~~**

2~~4~~.1. ***Strengthen*** ~~P~~***p***reparedness to and response for serious cross border health threats taking into account and coordinating with global initiatives: put in place common components of generic and specific preparedness planning, including for pandemic influenza, and report regularly on implementation of preparedness plans.

2~~4~~.2. ***Improve*** ~~R~~***r***isk assessment ~~capacity~~***and:*** ~~-~~close gaps in risk assessment capacities by providing additional capacities for scientific expertise and map existing assessments to improve coherence at Union level.

2~~4~~.3. Support capacity building against health threats in Member States: develop preparedness and response planning, public health response coordination, common approaches on vaccination; develop guidelines on protective measures in an emergency situation, guidelines on information and guides to good practice; set up a new mechanism for joint procurement of medical countermeasures; develop common communication strategies.

2~~4~~.4. Actions required by or contributing to the implementation of Union legislation in the fields of communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change. Such action may include activities aimed at ensuring the implementation, application, monitoring and review of that legislation.

2~~4~~.5. Fostering a health ***information and*** knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide- dissemination of the results of the Programme.

3~~1~~. ***Contributing to innovative, efficient and sustainable health systems: Identifying and*** ~~**D**~~***d*****eveloping** ~~**common**~~ **tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitating** ***the voluntary*** **up-take of innovation in healthcare** ***and in public health as well as to support public health capacity building*** ~~**in order to contribute to innovative and sustainable health systems**~~

3~~1~~.1. ~~Health technology assessment: **S**~~support ***voluntary*** European cooperation on Health Technology Assessment (HTA) under the European voluntary network on Health Technology Assessment set up by the Directive 2011/24/EU of the European Parliament and of the Council[6]. Facilitate the uptake of the results streaming from research projects supported under 7th Framework Programme and the in the longer term the activities which will be undertaken in the forthcoming research and innovation programmes 2014-2020 (Horizon 2020).

3~~1~~.2. ***Promote the voluntary uptake of h~~H~~***ealth innovation and e-Health~~:~~ ***by*** increasing the interoperability of patient registers and other e-Health solutions; support European cooperation on e-Health, notably on registries and uptake by health professionals. This will serve the European voluntary network on e-Health set up by the Directive 2011/24/EU of the European Parliament and of the Council.

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6 OJ L 88, 4.4.2011, p. 45.

3~~1~~.3. ***Support the sustainability of EU health workforce by*** ~~Health workforce:~~ develop***ing*** effective health workforce forecasting and planning in terms of numbers, scope of practice and skills, monitor mobility (within the Union) and migration of health professionals, establish efficient recruitment and retention strategies and capacity development.

3~~1~~.4. ***Provide expertise and share good practise to assist Member States undertaking*** ~~Decision making on~~ health systems reforms~~:~~ ***by*** set***ting*** up a mechanism for pooling expertise at Union level, to provide sound and evidence-based advice on effective and efficient investment in public health and health systems. Facilitate the uptake of the results streaming from research projects supported under the 7th Framework Programme and the in the longer term the activities which will be undertaken in the forthcoming research and innovation programme 2014-2020 (Horizon 2020).

3~~1~~.5. Support ***actions which address health issues in ageing society, including actions suggested by*** ~~for~~ the European Innovation Partnership on Active and Healthy Ageing in its three themes: innovation in awareness, prevention and early diagnosis; innovation in cure and care and innovation for active ageing and independent living.

3~~1~~.6. Actions required by or contributing to the implementation of Union legislation in the field of medical devices and cross border healthcare (e-Health and HTA). Such action may include activities aimed at ~~ensuring~~ ***facilitating*** the implementation, application, monitoring and review of that legislation.

3~~1~~.7. Fostering a health ***information and*** knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide-dissemination of the results of the Programme and including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC.

42. ***Facilitating access to better and safer healthcare for ~~EU~~Union citizens:*** **Increase access to medical expertise and information for specific conditions also beyond national borders and developing ~~shared~~ solutions and guidelines to improve healthcare quality and patient safety ~~in order to increase access to better and safer healthcare for EU citizens~~**

42.1. ~~Access: s~~***S***upport the establishment of a system of European Reference Networks to enable *inter alia* the mobility of medical expertise for patients with conditions requiring highly specialised care and a particular concentration of resources or expertise, like in the case of rare diseases, on the basis of criteria to be set under Directive on the application of patients' rights in cross-border healthcare (Directive 2011/24/EU)[7].

42.2 ~~Rare diseases: s~~***S***upport Member States, patient organisations and stakeholders by coordinated action at Union level in order to effectively help patients affected by rare diseases. This includes creation of reference networks (in compliance with point 2.1), information and registries for rare diseases based on ~~the~~ common criteria ~~of accreditation~~.

42.3. ~~Quality and safety: s~~***S***trengthen collaboration on patient safety and quality of healthcare, through, *inter alia*, implementing the Council Recommendation on patient safety and the prevention and control of healthcare-associated infections; exchange best practice on quality assurance systems; develop guidelines and tools to promote patient safety ~~and quality~~; increase the availability of information to patients on safety and quality, improve feedback and interaction between health providers and patients; support action to exchange knowledge and best practice on chronic diseases care, the response of health systems and research ~~including development of European guidelines~~.

42.4. ~~Safety: i~~***I***mprove the prudent use of antimicrobial agents in medicinal products and reduce the practices that increase antimicrobial resistance; reduce the burden of resistant infections and healthcare-associated infections and secure the availability of effective antimicrobials.

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7 OJ L 88, 4.4.2011, p. 45.

~~*4*~~*2*.5. Actions required by or contributing to the implementation of Union legislation in the fields of tissues and cells, blood, organs, medicinal products use and patients' rights in cross-border healthcare. Such action may include activities aimed at ***facilitating*** ~~ensuring~~ the implementation, application, monitoring and review of that legislation.

~~*4*~~*2*.6. Fostering a health ***information and*** knowledge system to contribute to evidence-based decision making including collecting and analysing health data and wide dissemination of the results of the Programme.

This list might be completed with additional actions of similar type and impact pursuing the specific objectives mentioned in Article 3.

ANNEX II

Indicative list of the relevant legislation referred to in Article 4 and Annex I

1. Blood, organs, tissues and cells

1.1. Directive 2002/98/EC of the European Parliament and the Council of 27January 2003,
setting standards of quality and safety for the collection, testing, processing, storage and distribution of human blood and blood components and amending Directive 2001/83/EC (OJ L 33, 8.2.2003, p. 30).

1.2. Directive 2010/45/EU of the European Parliament and the Council of 7 July 2010, on standards of quality and safety of human organs intended for transplantation (OJ L 207, 6.8.2010, p. 14).

1.3. Directive 2004/23/EC of the European Parliament and the Council of 31 March 2004, on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (OJ L 102, 7.4.2004, p. 48).
Only important basic legislation has been listed here; for other legislation relating to blood, organs, tissues and cells please see:
http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor3

2. Communicable diseases

2.1. Decision N° 2011/98/EC of the European Parliament and the Council of 24 September 1998, setting up a network for the epidemiological surveillance and control of communicable diseases in the Community (OJ L 268, 3.10.1998, p. 1).

2.2. Regulation (EC) No851/2004 of the European Parliament and of the Council of 21 April 2004, establishing a European Centre for Disease and Prevention and Control (OJ L 142, 30.4.2004, p. 1).

Only important basic legislation has listed here; for other legislation relating to diseases please see:
http://ec.europa.eu/health/communicable_diseases/key_documents/index_en.htm#anchor1

3. Tobacco products and advertisement

3.1. Directive 2001/37/EC of the European Parliament and the Council of 5 June 2001, on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco products (OJ L 194, 18.7.2001, p. 26).

3.2. Directive 2003/33/EC of the European Parliament and the Council of 26 May 2003, on the approximation of the laws, regulations and administrative provisions of the Member States relating to the advertising and sponsorship of tobacco products (OJ L 152, 20.6.2003, p. 16).

Only important basic legislation has been listed here; for other legislation relating to tobacco please see: http://ec.europa.eu/health/tobacco/law/index_en.htm

4. Patients' rights in cross-border health care

4.1. Directive 2011/24/EU of the European Parliament and the Council of 9 March 2011, on the application of patients' rights in cross-border healthcare (OJ L 88, 4.4.2011, p. 45).

5. Pharmaceutical products

5.1. Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004, laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1).

5.2. Council Regulation (EC) No 297/95 of 10 February 1995, on fees payable to the European Agency for the Evaluation of Medicinal Products (OJ L 35, 15.2.1995, p. 1).

5.3. Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001, on the Community code relating to medicinal products for human use (OJ L 311, 28.11.2001, p. 67).

5.4. Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999, on orphan medicinal products (OJ L 18, 22.1.2000, p. 1).

5.5. Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006, on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 378, 27.12.2006, p. 1).

5.6. Regulation (EC) No 1394/2007 of the European Parliament and of the Council of 13 November 2007, on advanced therapy medicinal products and amending Directive 2001/83/EC and Regulation (EC) No 726/2004 (OJ L 324, 10.12.2007, p. 121).

5.7. Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001, on the approximation of the laws, regulations and administrative provisions of the Members States relating to the implementation of good clinical practice in the conduct of clinical trials on the medicinal products for human use (OJ L 121, 1.5.2001, p. 34).

5.8. Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001,
on the Community code relating to veterinary medicinal products (OJ L 311, 28.11.2001, p.1).

5.9. Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009, laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council (OJ L 152, 16.6.2009, p. 11).

Only important basic legislation has been listed here; for other legislation relating to pharmaceutical products, please see:
Products for human use: http://ec.europa.eu/health/documents/eudralex/vol-1/index_en.htm
Products for veterinary use: http://ec.europa.eu/health/documents/eudralex/vol-5/index_en.htm

6. Medical devices

6.1. Council Directive 90/385/EC of the European Parliament and of the Council of 20 June 1990, on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

6.2. Council Directive 93/42/EC of the European Parliament and of the Council of 14 June 1993, concerning medical devices (OJ L 169, 12.7.1993, p. 1).

6.3. Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices (OJ L 331, 7.12.1998, p. 1).

Only important basic legislation has been listed here; for other legislation relating to medical devices please see: http://ec.europa.eu/health/medical-devices/documents/index_en.htm