

CIRCULAR Nº 5/2005

DEPENDENCIA: Agencia Española de Medicamentos y Productos Sanitarios

CONTENIDO: Información sobre Resoluciones del Comité de Salud Pública (Acuerdo Parcial), del Consejo de Europa, en materia de Farmacopea Europea.

AMBITO DE APLICACION: Asociación Española de fabricantes de Productos de Química Fina (Afaquim), Farmaindustria, Veterindustria, Asociación para el Autocuidado de la Salud (ANEFPP), Asociación Española de Farmacéuticos de la Industria (AEFI), Consejo General de Colegios de Farmacéuticos, Consejo General de Colegios de Médicos, Consejo General de Colegios Veterinarios de España, Sociedad Española de Farmacia Hospitalaria, Sociedad Española de Medicina Nuclear, Asociación Nacional de Especialistas de Radiofarmacia (Anerfa), Decanos de las Facultades de Farmacia de España, Reales Academias de Farmacia de Madrid y Barcelona, Direcciones de Salud de las Comunidades Autónomas.

España, desde 1987, es miembro de pleno derecho del Convenio para la Elaboración de una Farmacopea Europea.

Dicho Convenio, establece en su art. 1, que las Partes Contratantes se comprometerán a "adoptar las medidas necesarias para que las monografías que se aprueben en virtud de los artículos 6 y 7 del presente Convenio y que constituirán la Farmacopea Europea sean normas oficiales aplicables en sus respectivos países".

El mismo Convenio, en sus artículos 4 y 6, precisa que los órganos encargados de la elaboración de la Farmacopea Europea son el Comité de Salud Pública (Acuerdo Parcial), del Consejo de Europa y la Comisión de la Farmacopea Europea. El primero de ellos, fija los plazos en que deberán entrar en vigor en los territorios de las Partes Contratantes las decisiones de carácter técnico, que toma la Comisión en sus sesiones.

Teniendo en consideración las decisiones técnicas que la Comisión ha tomado en su sesión de marzo de 2005, y vistas las Resoluciones AP/CSP (05) 1, AP/CSP (05) 2 y AP/CSP (05) 3, emitidas por el Consejo de Salud Pública (Acuerdo Parcial), del Consejo de Europa, la Agencia Española de Medicamentos y Productos Sanitarios informa a los usuarios de la farmacopea de lo siguiente:

El Consejo de Salud Pública (Acuerdo Parcial), del Consejo de Europa, a través de las Resoluciones AP/CSP (05) 1, AP/CSP (05) 2 y AP/CSP (05) 3, comunica su decisión de fijar como fecha de **entrada en vigor de los suplementos 5.4, 5.5 y 5.6 de la 5ª Edición de la Farmacopea Europea**, el **01/04/06**, **01/07/06** y el **01/01/07** respectivamente.

Madrid, 29 de Septiembre de 2005

LA DIRECTORA DE LA AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

M^a. Val DÍEZ RODRIGÁLVAREZ

COUNCIL OF EUROPE
PUBLIC HEALTH COMMITTEE
(Partial Agreement)

RESOLUTION AP-CSP (05) 1

*(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP)
on 31 March 2005)*

The Public Health Committee (Partial Agreement) (CD-P-SP) consisting, for the purposes of the Convention on the Elaboration of a European Pharmacopoeia, of delegations appointed by the Parties to the said Convention, namely the delegations of Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Portugal, Romania, Serbia and Montenegro, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the Former Yugoslav Republic of Macedonia”, Turkey, the United Kingdom, and the European Community,

Considering that, under Article 1 of the Convention, the Parties have undertaken progressively to elaborate a Pharmacopoeia which shall be common to the countries concerned and which shall be entitled “European Pharmacopoeia”, and to take the necessary measures to ensure that the monographs constituting the European Pharmacopoeia shall become official standards applicable within their respective countries;

Having regard to Article 4, paragraph 3, of the Convention, which makes the Public Health Committee responsible for fixing the time-limits within which decisions of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the respective Parties;

Having regard to the decision taken by the European Pharmacopoeia Commission to elaborate a new edition of the European Pharmacopoeia, i.e., the 5th edition, which will be updated by a supplement following each session of the Commission;

Having regard to the recommendation on the fixing of the date of implementation of the fourth supplement of the 5th edition within the territories of the Parties, adopted on 30 March 2005 by the European Pharmacopoeia Commission, in accordance with the provisions of Article 6, paragraph d, of the Convention;

Has decided to set 1st April 2006 as the date for implementation of the texts constituting the fourth supplement of the 5th edition of the European Pharmacopoeia entitled “Supplement 5.4” and bearing the date “04/2006”.

COUNCIL OF EUROPE
PUBLIC HEALTH COMMITTEE
(Partial Agreement)

RESOLUTION AP-CSP (05) 2

*(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP)
on 31 March 2005)*

The Public Health Committee (Partial Agreement) (CD-P-SP) consisting, for the purposes of the Convention on the Elaboration of a European Pharmacopoeia, of delegations appointed by the Parties to the said Convention, namely the delegations of Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Portugal, Romania, Serbia and Montenegro, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the Former Yugoslav Republic of Macedonia”, Turkey, the United Kingdom, and the European Community,

Considering that, under Article 1 of the Convention, the Parties have undertaken progressively to elaborate a Pharmacopoeia which shall be common to the countries concerned and which shall be entitled “European Pharmacopoeia”, and to take the necessary measures to ensure that the monographs constituting the European Pharmacopoeia shall become official standards applicable within their respective countries;

Having regard to Article 4, paragraph 3, of the Convention, which makes the Public Health Committee responsible for fixing the time-limits within which decisions of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the respective Parties;

Having regard to the decision taken by the European Pharmacopoeia Commission to elaborate a new edition of the European Pharmacopoeia, i.e., the 5th edition, which will be updated by a supplement following each session of the Commission;

Having regard to the recommendation on the fixing of the date of implementation of the fifth supplement of the 5th edition within the territories of the Parties, adopted on 30 March 2005 by the European Pharmacopoeia Commission, in accordance with the provisions of Article 6, paragraph d, of the Convention;

Has decided to set 1st July 2006 as the date for implementation of the texts constituting the fifth supplement of the 5th edition of the European Pharmacopoeia entitled “Supplement 5.5” and bearing the date “07/2006”.

COUNCIL OF EUROPE
PUBLIC HEALTH COMMITTEE
(Partial Agreement)

RESOLUTION AP-CSP (05) 3

*(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP)
on 31 March 2005)*

The Public Health Committee (Partial Agreement) (CD-P-SP) consisting, for the purposes of the Convention on the Elaboration of a European Pharmacopoeia, of delegations appointed by the Parties to the said Convention, namely the delegations of Austria, Belgium, Bosnia and Herzegovina, Bulgaria, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Portugal, Romania, Serbia and Montenegro, the Slovak Republic, Slovenia, Spain, Sweden, Switzerland, “the Former Yugoslav Republic of Macedonia”, Turkey, the United Kingdom, and the European Community,

Considering that, under Article 1 of the Convention, the Parties have undertaken progressively to elaborate a Pharmacopoeia which shall be common to the countries concerned and which shall be entitled “European Pharmacopoeia”, and to take the necessary measures to ensure that the monographs constituting the European Pharmacopoeia shall become official standards applicable within their respective countries;

Having regard to Article 4, paragraph 3, of the Convention, which makes the Public Health Committee responsible for fixing the time-limits within which decisions of a technical character relating to the European Pharmacopoeia shall be implemented within the territories of the respective Parties;

Having regard to the decision taken by the European Pharmacopoeia Commission to elaborate a new edition of the European Pharmacopoeia, i.e., the 5th edition, which will be updated by a supplement following each session of the Commission;

Having regard to the recommendation on the fixing of the date of implementation of the sixth supplement of the 5th edition within the territories of the Parties, adopted on 30 March 2005 by the European Pharmacopoeia Commission, in accordance with the provisions of Article 6, paragraph d, of the Convention;

Has decided to set 1st January 2007 as the date for implementation of the texts constituting the sixth supplement of the 5th edition of the European Pharmacopoeia entitled “Supplement 5.6” and bearing the date “01/2007”.