MINISTERIO DE SANIDAD Y CONSUMO

agencia española de **medicamentos y productos sanitarios**

CIRCULAR Nº 10/2004

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: Afaquim, Farmaindustria, Veterindustria, Asociación para el Autocuidado de la Salud (ANEFP), Asociación Española de Farmaceúticos 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 sus sesiones de noviembre de 2003 y de marzo de 2004, y vistas las Resoluciones AP/CSP (04) 1, AP/CSP (04) 2, AP/CSP (04) 3 y AP/CSP (04) 4, 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 (04) 1, AP/CSP (04) 2 y AP/CSP (04) 3, comunica su decisión de fijar como fecha de **entrada en vigor de los suplementos 5.1, 5.2 y 5.3 de la 5ª Edición de la Farmacopea Europea,** el **01/04/05**, **01/07/05** y el **01/01/06** respectivamente.

El Consejo de Salud Pública (Acuerdo Parcial), del Consejo de Europa, a través de la Resolución AP/CSP (04) 4, comunica su decisión de fijar como fecha de **supresión de la Farmacopea Europea de los siguientes capítulos,** el **01/01/05.**

2.6.3 *Ensayo de virus extraños usando huevos embrionarios,*
2.6.4 *Ensayo del virus de la leucosis,*
2.6.5 *Ensayo de virus extraños usando cultivos celulares,*
2.6.6 *Ensayo de agentes extraños usando polluelos,*

Madrid, 31 de mayo de 2004

EL DIRECTOR DE LA AGENCIA ESPAÑOLA
DE MEDICAMENTOS Y PRODUCTOS SANITARIOS

Carlos Lens Cabrera

MINISTERIO
DE SANIDAD
Y CONSUMO
Agencia española del
medicamentos y
productos sanitarios

COUNCIL OF EUROPE

PUBLIC HEALTH COMMITTEE

(Partial Agreement)

RESOLUTION AP-CSP (04) 1

(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP) on 31 March 2004)

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, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, 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 Union,

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 first supplement of the 5th edition within the territories of the Parties, adopted on 30 March 2004 by the European Pharmacopoeia Commission, in accordance with the provisions of Article 6, paragraph d, of the Convention;

Has decided to set 1st April 2005 as the date for implementation of the texts constituting the first supplement of the 5th edition of the European Pharmacopoeia entitled "Supplement 5.1" and bearing the date "04/2005".

COUNCIL OF EUROPE

PUBLIC HEALTH COMMITTEE

(Partial Agreement)

RESOLUTION AP-CSP (04) 2

(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP) on 31 March 2004)

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, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, 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 Union,

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 second supplement of the 5th edition within the territories of the Parties, adopted on 30 March 2004 by the European Pharmacopoeia Commission, in accordance with the provisions of Article 6, paragraph d, of the Convention;

Has decided to set 1st July 2005 as the date for implementation of the texts constituting the second supplement of the 5th edition of the European Pharmacopoeia entitled "Supplement 5.2" and bearing the date "07/2005".

COUNCIL OF EUROPE

PUBLIC HEALTH COMMITTEE

(Partial Agreement)

RESOLUTION AP-CSP (04) 3

(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP) on 31 March 2004)

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, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, 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 Union,

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 third supplement of the 5th edition within the territories of the Parties, adopted on 30 March 2004 by the European Pharmacopoeia Commission, in accordance with the provisions of Article 6, paragraph d, of the Convention;

Has decided to set 1st January 2006 as the date for implementation of the texts constituting the third supplement of the 5th edition of the European Pharmacopoeia entitled "Supplement 5.3" and bearing the date "01/2006".

COUNCIL OF EUROPE

PUBLIC HEALTH COMMITTEE

(Partial Agreement)

RESOLUTION AP-CSP (04) 4

(adopted by the Public Health Committee (Partial Agreement) (CD-P-SP) on 27 April 2004)

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, Croatia, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Luxembourg, 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 Union,

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 adoption on 26 November 2003 by the European Pharmacopoeia Commission of the two methods of analysis:

- 2.6.24 *Avian viral vaccines: tests for extraneous agents in seed lots,*
- 2.6.25 *Avian live virus vaccines: tests for extraneous agents in batches of finished product,*

which incorporate revised versions of texts 2.6.3, 2.6.4, 2.6.5 and 2.6.6;

Having regard to the recommendation adopted on 26 November 2003 by the European Pharmacopoeia Commission, in accordance with the provision of Article 6, paragraph d of the Convention, which concerns the fixing of the date on which the methods of analysis:

- 2.6.3 *Test for extraneous viruses using fertilised eggs,*
- 2.6.4 *Test for leucosis viruses,*
- 2.6.5 *Test for extraneous viruses using cell cultures,*
- 2.6.6 *Test for extraneous agents using chicks,*

shall cease to form part of the European Pharmacopoeia;

Resolves to set at 1 January 2005 the date on which the methods of analysis 2.6.3, 2.6.4, 2.6.5 and 2.6.6 shall cease to form part of the 5th Edition of the European Pharmacopoeia.